



Health Innovation North West Coast

Your UK Strategic Market Access Partner



As NHS market access specialists, **Health Innovation NWC** can help you demonstrate the benefits and value of your product to patients, care providers and payers through a comprehensive bespoke package of support

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The National Health Service (NHS) is the largest integrated healthcare system in the world, treating almost 1 million patients daily. The NHS has unique, unified data capabilities, including clinical data and well defined patient cohorts essential to generating the real-world evidence that decision makers are increasingly seeking.

As the fifth largest employer in the world, the NHS employs 1.7 million workers across the UK. The NHS net expenditure is in excess of £130bn and the NHS spends £6bn annually on health technologies deployed across over 200 hospitals and over 7,000 primary care practices.

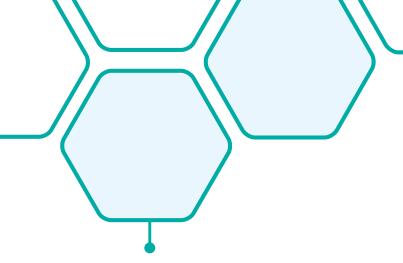
The UK medical technology sector is a thriving ecosystem of researchers, scientists, engineers, designers and NHS clinicians working in an established industrial base. Together they steer development of a new technology from innovation, to design and manufacture, and finally to the patient. Working with the NHS in England offers significant market opportunities for life science companies as well as a globally respected ecosystem for conducting research and development.

UK Government commitment to Life Science Sector

The UK has a long-term industrial strategy providing billions of UK pounds of funding to deliver the next generation of life changing treatments and technologies. The future of the already highly productive science base is secured by a commitment to increase R&D spending to 2.4% of GDP by 2027 equivalent to over £95bn.

The right environment to grow your business

The UK offers leading-edge research and innovation platforms to test, bring to market and commercialise the next generation of discoveries. It is one of the world's easiest places to do business, and offers one of the best tax environments for R&D.



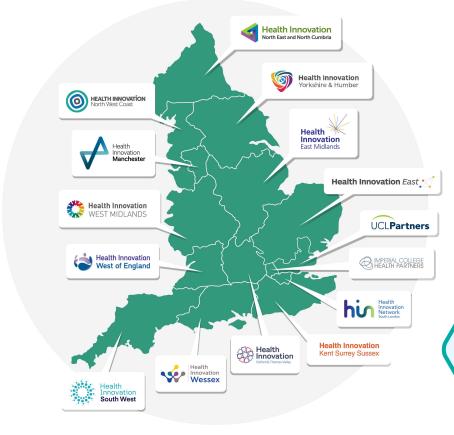
About us

Health Innovation NWC is one of 15 local health innovation networks across England. Collectively, we form the Health Innovation Network, the innovation arm of the English NHS. We are part of a network of organisations whose role is to spread healthcare innovations regionally and nationally, which can improve the quality of health and care and drive efficient and effective care delivery.

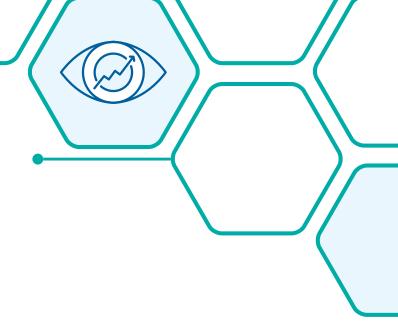
Our network connects expertise and knowledge across the NHS in the UK, other public sector organisations, academia, businesses and the voluntary sector.

Over the last three years we have supported 50 international businesses, working with a range of UK partners and our Health Innovation Network to achieve rapid uptake of innovations and initiatives to benefit the population nationally.

Health Innovation NWC works with health system partners to deliver transformation and improvement in healthcare. We deliver a wide range of market access support to small and medium-sized businesses whose healthcare products have potential to transform healthcare delivery in north west of England and the rest of the UK.







Market Engagement

As the innovation arm of the NHS, Health Innovation NWC can help your company understand and navigate the complexities of the UK healthcare landscape, connecting you with key players from public, private, third sector and patient organisations. Our deep understanding of the NHS allows us to quickly identify challenges and opportunities presented by demographic and financial pressures to care pathways of interest to international companies.

We identify and facilitate engagement with key opinion leaders, policy-makers, commissioners, decision makers and influencers, as well as the research infrastructure across the UK and can leverage support to help Innovators to engage effectively with all parts of the UK public and private healthcare systems.

Our <u>team</u> is composed of experts in innovation adoption and senior health and care practitioners. This gives us access to key opinion leaders and researchers as well as medical societies, top clinicians in every discipline, hospital managers, commissioners, regulators and policy makers.

Furthermore, we work closely with our partners at the National Institute for Healthcare Research, the research arm of the NHS, to help international companies connect with national and regional clinical researchers. We provide access to research design support to design, set up and deliver high quality research in both the NHS and the wider health and social care environment, across England.

It's been an absolute pleasure to work with Health Innovation NWC. They are a true thought-partner that goes the extra mile to support achievement of your goals. They have excellently facilitated our market access strategy including building health economic evidence, partnerships with key stakeholders and more. Thanks to their support we were able to quickly and successfully enter the UK market. I highly recommend them to any business that is looking to do the same.

Dion Osemwengie HemoClear BV



Market Opportunity Analysis

Health Innovation NWC has privileged access to unified NHS patient datasets and sophisticated health informatics tools and analysis expertise, to mine electronic health records databases in the UK, to map current pathways of care for patients treated across the UK's health and care system.

We regularly provide international companies with access to Hospital Episode Statistics (HES)*, as well as and more importantly, extensive access to experience in analysing and presenting the derived data to explain the narrative behind the numbers.

Through analysis of secondary care data (HES data) we can map patient pathways, assess health resource utilisation data, health outcomes and associated costs at the national and regional level to help international companies understand:

- Disease burden and unmet need across a wide range of health conditions;
- Patient pathways for a wide range of health conditions;
- Current service provision (public and private);
- Diagnostic tests and how they are being used;
- Reimbursement regulations and the revenues generated by provider organisations;
- The addressable market (public and private providers where patients referred under NHS contract and treated in private hospital);
- Demand/supply characteristics (across care pathways);
- The competitive landscape;
- Service provision that should be available to meet demand including variations in referrals patterns at local level and access pinch points.

We can also facilitate access to Clinical Practice Research Data (*link*), sourced from a UK-wide network of over 1,700 primary care practices and include 45 million patients of which 13 million are currently registered active patients with at least 20 years of follow up for 25% of the patients. The CPRD database contains coded and anonymised Electronic Health Record (HER) data from primary care practices capturing information including:

- Demographic data;
- Diagnoses and symptoms;
- Drug exposures;
- Vaccination history;
- Laboratory tests;
- Referrals to hospital and specialist care.

We highly recommend Health Innovation NWC's services to other startups in development. Despite the challenges posed by the pandemic, thanks to their support we have achieved important market access and reimbursement milestones, including securing specialised distributors in the UK.

Edouard Bustin

Head of Sales at Implicity

^{*} HES contains all activities undertaken in all NHS Hospitals in England including ICD10 and OPCS codes, this covers c80% of the UK population. We can provide access to a ten-year dataset, updated monthly from NHS Digital.

Value Proposition Development

Health Innovation NWC can provide support to refine and validate your evidence based, value proposition so that it demonstrates a clear understanding of the needs of target UK decision makers (payers).

We can provide insights and guidance on how to articulate and define a healthcare problem, its associated burden and validate the unmet need for the proposed product or service. We support you to explore ways to qualify and quantify the problem to capitalise on open areas of opportunity in the UK market.

We can also provide expert advice on the development of evaluation methods to determine whether your product is unique and compelling and how to generate the necessary evidence that will support future claims that the proposed solution performs better than the alternatives.

Health Innovation NWC can support the construction of a healthcare value proposition for the new product/service that will include:

- Market viability analysis and Value Proposition validation.
- 'Top line' projections of anticipated value to NHS (Clinical Outcomes, Safety, Experience, Efficiency).
- 3. Recommendations for future adoption support.

Health Innovation NWC can help you understand fundamental market dynamics enabling you to think through the specific conditions of the UK healthcare market, in order to determine where your product is likely to be most successful.

We can help you develop an understanding of where the best opportunities are for your product or your company to pursue (Market Potential) and we can assist you to define the strengths, weaknesses, opportunities and threats your business faces in the UK market, relative to the competition (barriers to entry).

Using the outputs from a review of your Business Model, we provide structure and guidance to the discovery of new product opportunities in the market (matching of opportunities to those of your company's resources, plans and strategies). We help you to develop an understanding of the UK market's readiness and willingness to invest and adopt a new product (identifying market requirements).



NHS Business Case Development

Health Innovation NWC supports the development of your NHS Business Case. We regularly help companies to develop the correct structure and format so that they are able to effectively demonstrate a clear rationale, the benefits to patients, the service and provider organisation, financial effectiveness and affordability of their product.

We provide comprehensive support covering the following key elements necessary to ensure that your NHS business case is robust and offers the best chance of success:

- Constructing an executive summary;
- Setting the strategic context;
- The case for change and key objectives;
- Options appraisal and preferred option;
- Capital and revenue implications;
- Affordability;
- Options appraisal and preferred option;
- NHS approval processes.

Procurement

Like most public bodies, NHS organisations are "contracting authorities" subject to the requirements of UK public procurement law. Regulations are in place to ensure that all contracts over a certain value are opened up to the market to allow all providers a chance to offer the contract requirements. We can help international companies identify these opportunities that will allow you to bid for contracts to sell your product.

There are different rules for contracting authorities depending on whether they are buying clinical services or non-clinical services such as a technology, product or service. Even where the value of a contract is lower than these thresholds, contracting authorities may decide to run competitive tenders anyway.

We can engage with NHS procurement specialists to secure a tender requirements waiver for development of innovative technologies, products and services through evaluations or trials with NHS organisations This can be an effective way of securing partnerships with NHS organisations.

Health Innovation NWC can support international companies to fully understand public contract regulations that have fundamentally changed the way procurement works in the UK. We can help you to develop a full understanding of how NHS procurement selection processes work and what commissioning authorities are looking for in a supplier and how the new regulations provide clearer opportunities.

Specifically, we can help you:

- Find out who the key decision makers are when it comes to awarding contracts in your product category and type of business;
- Engage with the right decision-makers and help build a relationship;
- Present the 'right' argument to the 'right' people;
- Identify opportunities before they are notified, and even help shape tender opportunities by participating in lawful soft market engagement events.



Patient Engagement

Health Innovation NWC believes that 'Every Voice Matters' when products and services are being developed for the UK healthcare system. We can help businesses seeking the input of specific patient groups to find those groups they are keen to engage with. This helps to ensure that crucial insights are captured and considered throughout the various stages of research and product development, significantly reducing the risk of market failure.

We can provide you with unrivalled access to our specialist team who are dedicated to ensuring that the views of patients and the wider public are considered in all aspects of product development. This activity is designed to ensure that the unique perspectives of those individuals who are likely to encounter your innovation in our healthcare system are captured and considered at all stages of product development, implementation and adoption. Our Patient and Public Engagement Leads are skilled in identifying and engaging with people from all walks of life, involving them in the development of healthcare innovations to ensure that products and services are co-developed with people most likely to benefit from them.

Our team of dedicated professionals are skilled in:

- Identifying and engaging with specific groups of patients for each unique project;
- Gathering consent from patients prior to engagement;
- Facilitating workshops designed to capture and record specific patient perspectives;
- Advising businesses on how best to frame their questions to each patient group;

- Providing summary findings gathered from target patient groups;
- Ensuring that patients are protected by the rules of data protection throughout the engagement process.

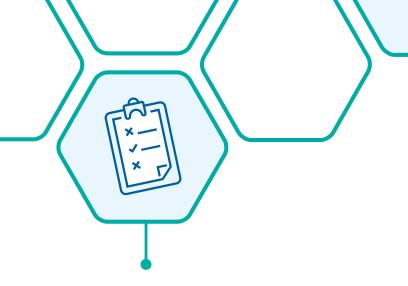
For a young growing company, entering a new market is a real challenge, hence the need to be well-supported to facilitate market access and minimise the risk of unsuccessful prospecting.

The various support services and the strong network provided by Health Innovation NWC over the past 12 months have been critical. As a result of the support provided, we successfully deployed our first robotic system in the UK despite the difficult business environment posed by the pandemic.

I would like to thank Health Innovation NWC for its valuable contribution to this success story.

Philippe Homsi Export Director





Evaluation Planning

Health Innovation NWC supports international companies to develop a scalable and systematic approach to product or service evaluation in the UK. Deploying an evidence-based evaluation process model, five-level framework and operating standards to capture evaluation metrics from simple satisfaction scores to clinical outcomes and financial impact.

We can support you with protocol design to collect both qualitative and quantitative data during evaluation to report performance, isolate the effects of a product/service from other influences – resulting in credible metrics and return on investment (ROI) reports accepted by financial executives and other NHS stakeholders.

Health Innovation NWC provides guidance and support to apply an evaluation framework and process model in:

- Evaluation planning;
- Data collection;
- Data analysis;
- Evaluation reporting to key opinion leaders, NHS decision makers and influencers.

Regulation

Navigating regulatory pathways, evidence requirements and routes to compliance are a universal challenge facing international medical technology businesses. We provide access to advice to enable you to develop specific strategies to secure access to the UK market, by understanding the complex and changing nature of regulatory affairs and compliance matters relating to healthcare products and services in the UK.

Our support aims to give you insight into the following areas:

- Regulatory strategy: UK regulatory environment and requirements. This support will focus on how regulatory strategy underpins business planning, evaluating regulatory requirements alongside market access evidence to build a holistic R&D plan, practical guidance/advice on persons responsible for regulatory compliance (PRRC), accessing UK Approved Bodies and interacting with MHRA and other regulatory bodies.
- Gap assessment including how to undertake a gap analysis on your company's specific products and determine gaps against specific requirements.
- Remediation planning including how to break down a gap assessment into a list of tasks, actions, specific methodology, acceptance criteria, testing options, etc.

The overarching aim of our support is to educate international businesses and enable them to become more self-sufficient and knowledgeable about UK regulatory requirements.





Health Economic Analysis

Health Innovation NWC can provide international companies with access to advice and support with economic evaluation undertaken by our respected, internationally recognised and independent health economics partner York Health Economics Consortium (YHEC) (https://yhec.co.uk/).

Expertise can be provided to:

- Prepare submissions for national reimbursement via health technology assessment (HTA) agencies such as National Institute for Clinical Excellence (NICE) (https://www.nice.org.uk/);
- Develop an economic case to local NHS decision makers;
- Demonstrate potential cost-effectiveness in order to inform clinical study design, funding applications or price setting in the UK market.

Reimbursement

Health Innovation NWC can assist international companies to understand how the adoption of innovative health technologies can be incentivised at both local national level by health service commissioners. This includes supporting access to funding initiatives that enables patient access to new promising technologies and treatments that are not yet funded by the NHS, but nonetheless show significant promise for the future.

We help companies understand the NHS Tariff Payment System, as well as different payment incentives to support better care. We also help companies to access a wide range of incentives and rewards for healthcare innovations and the opportunities they present.

Investment Support

We can provide access to a network of UK investors with a track record of investing in life science and healthcare technologies, products and services. Through our partners, this includes access to teams of experts who can look to match international businesses with the most appropriate, values-aligned high-net-worth individual investors and institutional investors. We can also provide you with access to specialist advice, insights and analysis to help you prepare for future fundraising.

Finally, we can help you prepare to engage with stakeholders and investors through professional pitch and presentation training to ensure that you most effectively engage with audiences and ensure your offering has a persuasive impact when engaging with potential UK clients, partners and funders.





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