Developing medical technologies for the NHS: working in partnership with industry

A report of a workshop held at the Royal College of Anaesthetists in December 2016 coordinated by the Royal College of Anaesthetists and the National Institute for Health Clinical Research Network Specialty Groups for: Anaesthesia, Perioperative Medicine and Pain Management; Critical Care; and Injuries and Emergencies.
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Note: the views expressed in this document are not necessarily those of the National Institute for Health Research
Introduction

The National Institute for Health Research (NIHR) is one of the most integrated health research systems in the world. Established by the Department of Health, the NIHR aims to improve the health of the nation and to make a significant contribution to the UK economy by making the NHS a strong and effective partner for the Life Sciences industry.

The overarching goal of Medical Technology (MedTech) is to improve health through research and innovation. MedTech covers a wide range of technologies from single use, high volume, minimally-regulated medical consumables to specially-made implantable devices that need to pass through several regulatory and health technology assessment processes to be adopted at scale in the NHS. The scale of the activity in the UK is substantial; there are over 3,300 MedTech companies in the UK and Ireland, employing around 75,000 people, turning over £17bn with an estimated 8% spend on R&D. Many MedTech companies are small or medium-sized enterprises (SMEs). The processes by which technologies are developed by SMEs, subsequently evaluated to ensure they meet a real clinical need effectively, and then procured at scale by the NHS, are perceived as challenging, particularly in comparison with the Pharmaceutical industry.

This report summarises a series of presentations and discussions which took place at a workshop jointly organised by the Royal College of Anaesthetists and the NIHR Clinical Research Network Specialty Groups: Anaesthesia, Perioperative Medicine and Pain Management, Critical Care, and Injuries and Emergencies. The report reviews the innovation landscape in the context of the UK Life Sciences Strategy and aims to help industry partners navigate the various elements of NHS innovation infrastructure. Case studies illustrate how to achieve clinical engagement in order to reduce the risk of late-stage failure. A short summary of further suggestions concludes the report.

Medical Technology for the NHS; strategic drivers

The UK MedTech landscape will need to adapt if it is to survive in the face of major health trends including: the changing care needs of an ageing population, the increasing prevalence of multi-morbidity and unsustainable cost inflation. Effective responses to these challenges will include the use of technology to improve care pathways, incentivising innovation, an increasing focus on tele-diagnosis, greater use of mobile technologies to support public health and disease prevention, and improved intra-industry and industry-government collaboration. The NHS landscape and associated processes for gathering and reviewing evidence for the effectiveness of new medical technologies, and subsequent procurement, can seem complex and difficult to navigate. Uptake by the NHS of proven medical technologies can be patchy and slow.

The soon-to-be-released UK Life Sciences strategy is expected to set out an ambition to make the UK the world’s leading life sciences hub, focused on key technologies. Meeting this aim will require even stronger partnership working between technology companies and Universities, the NHS, National Institute for Care and Excellence, Medicine and Healthcare products Regulatory Agency, Health Research Authority, Innovate UK and others. The strategy will build on the UK’s existing asset base and strengths in emerging technologies
and capitalise on a range of opportunities including NHS collaboration and uptake, digital and data innovation, science and manufacturing bases and the availability of skilled people.

Addressing a clear clinical need is key to the successful development of medical technology. This requires close partnership working between technologists, clinicians and commissioners of health care from the earliest stages of product development, if expensive late stage product failure is to be avoided. To be followed by the garnering of evidence for effectiveness, using a variety of approaches.

Global challenge

Antimicrobial resistance is a major global public health challenge and an NIHR research priority for which research has now been commissioned in response to recent NICE guidance. An important aim is to reduce over-diagnosis/treatment of suspected serious infections (sepsis) based on evidence from NHS-wide definitive pragmatic trials. These trials consider which rapid laboratory tests are available (there is a limited clinical evidence-base); clinical effectiveness (including safety); cost effectiveness and embedded process evaluations to understand clinical behaviour, with a 5-year horizon for patient impact, responding to patient need. Current health technology assessment programmes include those studying rapid (non-culture) pathogen diagnostics (blood), rapid tests for fungal infection, rapid acute inflammation diagnostics (plasma), and biomarker-guided duration of antibiotic treatment in hospitalised patients with sepsis. There is a need for delivering safer care with improved precision (Ombudsman) and a framework for high-value (disruptive) in-vitro diagnostics and an unmet need for improvements in clinical evidence (NICE) and new NHS-wide clinical trials (NIHR commissioned).

NICE guidance for MedTech often examines interventional procedures. An assessment of safety and efficacy occurs following input from specialist advisors and organisations, and a detailed literature analysis. This leads to a provisional decision in one of four categories: ‘standard’, ‘special’, ‘research only’ or ‘do not do’, with final guidance only being issued following public consultation. Provision of evidence to the standards required by NICE can be challenging for MedTech companies, particularly SMEs.

In recognition of these challenges, the UK government’s Accelerated Access Review sets out six areas where specific improvements are suggested, including:

- an enhanced horizon scanning process
- creation of an accelerated access pathway for products recognised as potentially transformative
- simpler and clearer routes to market
- a more rapid assessment process for technologies which exploits digital technology
- organisational incentives to accelerate uptake of innovative technologies
- better alignment of national bodies to accelerate innovation

**NIHR and medical technology**

Working with other national health research funders, NIHR’s primary focus is on evaluation but it also funds innovation of technologies that are close to clinical deployment, and research into accelerating adoption. NIHR invests more than £0.5bn per annum in NHS infrastructure to support clinical research at all points in the development pipeline and this NIHR clinical research infrastructure provides medical technology companies with numerous opportunities for clinical evaluation.

The [NIHR Office for Clinical Research Infrastructure (NOCRI)](https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/nihr-office-for-clinical-research-infrastructure/) helps industry navigate the NIHR system and provides industry partners with access to clinical expertise and capabilities at individual NIHR centres, unique multi-centre collaborations in early technology design and clinical input enabling early phase clinical research in specific therapeutic areas.
NOCRI facilitates rapid access to NIHR clinical research infrastructure through an initial meeting with a company, the identification of relevant NIHR infrastructure and gathering expressions of interest. They set up meetings between companies and investigators/academics/clinicians and initiate collaborative projects. This work is supported by standard agreements and templates.

A key element of the clinical research infrastructure is the NIHR Clinical Research Network (CRN)², which comprises a national network of 15 Local Clinical Research Networks (LCRNS) in England, over 400 research-active clinicians across 30 specialty areas and a network of engaged patients.

These arrangements provide flexible, clinically-informed, deployment of funding which covers the NHS support costs related to research, including commercial studies. The LCRNs and specialty groups together manage the delivery of these research studies. NIHR CRN maintains close working relationships with the devolved nations and with other cognate elements of the health system. For example, the MEDConNecT³ North Initiative for North East and North Cumbria entails a partnership between the Academic Science Health Network and the NIHR LCRN for the North East and North Cumbria. This partnership facilitates interaction between the NHS and MedTech through nominated manager support and expert steering group advice.

The scale of NIHR CRN activity is illustrated in the box below (figures from 2016/17 CRN key statistics⁴):

- Nearly 35,000 participants recruited to commercial contract studies in 2016/17
- UK globally ranked in second place for number of MedTech studies
- Currently 11.4% of commercial contract studies undertaken with MedTech companies funded/sponsored by a MedTech company
- 1326 non-commercial and 729 commercial studies added to NIHR CRN portfolio
- 73% of NIHR CRN commercial studies recruited to time and target

A second key element of NIHR infrastructure for MedTech is the network of NIHR Health

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² [https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/](https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/)


⁴ [https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/key-statistics.htm](https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/key-statistics.htm)
Technology Collaboratives (HTCs)\(^5\) in England. HTCs work in a number of different therapy areas with a particular focus on medical technology.

HTCs are having increased impact and reach:
- rise in the number of company collaborations — from 236 in 2013/14 to 354 in 2014/15
- number of active projects — from 76 in 2013/14 to 151 to 2014/15
- leveraged approximately £49.7 million in 2013/14 and £80.5 million in 2014/15.

**The NIHR MindTech HTC** (Nottinghamshire Healthcare NHS Foundation Trust) is helping accelerate the development, evaluation and adoption of technology for mental health and dementia.

**The NIHR Trauma Management HTC** (University Hospitals of Birmingham NHS Foundation Trust) is providing translation of technology from concept to trauma care across the themes of immediate, secondary and regeneration care and rehabilitation translation.

**The NIHR Cardiovascular HTC** (Guy’s and St Thomas’ NHS Foundation Trust) is helping identify, encourage and facilitate development of medical devices and technology-led solutions that improve the diagnosis, treatment and well-being of patients.

There are four **NIHR Diagnostic Evidence Co-operatives (DECs)**\(^6\): Imperial College Healthcare NHS Trust, Newcastle upon Tyne NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust and Oxford Health NHS foundation Trust. Their focus is on in-vitro diagnostics in areas including cancer, cardiovascular disease, infectious diseases, liver diseases, musculoskeletal diseases, renal diseases and primary care.

An example of an **NIHR DEC initiative is the in vitro diagnostics evidence generation pathway**\(^7\) described below:

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\(^5\) [https://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/healthcare-technology-co-operatives.htm](https://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/healthcare-technology-co-operatives.htm)


The NIHR HTCs and DECs will be succeeded by a single consolidated [NIHR platform for medical technology and in-vitro diagnostics (MICS)](https://www.nihr.ac.uk/funding-and-support/funding-to-provide-nihr-facilities/medtech-and-in-vitro-diagnostic-co-operatives.htm) in January 2018, with a very strong brief to engage with MedTech.

A further element of NIHR infrastructure are the [thirteen NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs)](https://www.nihr.ac.uk/about-us/how-we-are-managed/our-structure/infrastructure/collaborations-for-leadership-in-applied-health-research-and-care.htm) which focus on regional implementation of applied health research including the evaluation of technologies such as tele-health.
The **NIHR Innovation Observatory (NIHRIO)**\(^\text{10}\) is an independent research team at the Newcastle University and incorporated as a research programme within the NIHR. NIHRIO applies state-of-the-art data analytics to explore trends in health innovation across drugs, medical technologies, diagnostic tools and healthcare services. This offers academia and industry unique insights to identify areas to develop that can provide better healthcare and allow an opportunity for new innovations to be used in practice more rapidly. NIHRIO supplies information to key NHS policy and decision-makers and research funders about emerging health technologies that may have a significant impact on patients or the provision of health services in the near future.

**Accelerating evaluation in the NHS**

The NIHR CRN provides free-of-charge support to help the life-sciences industry deliver high quality research in England.

As part of the wider NIHR, the CRN invests over £300 million per year into research infrastructure. This infrastructure provides industry with unparalleled access to, and understanding of, the NHS research environment. It includes over 10,000 dedicated clinical research professionals who work across all therapeutic areas.

Proactively supporting the life-sciences industry to rapidly set-up and deliver clinical research to time and target is a high priority for the CRN. To facilitate this, the CRN has developed a package of free services and support tools which MedTech can shape to meet specific needs.

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**Feasibility**

With unrivalled access to the latest NHS clinical research performance and capacity information, plus clinical expertise, whether you have a synopsis or draft final protocol, NIHR CRN can help identify or confirm potential study sites and targets.

**Study set-up**

We are constantly working to improve the set-up and delivery of clinical research studies in the NHS. Our tools have been developed in collaboration with the clinical research community to efficiently support your study set-up.

**Performance Management**

Our collaborative approach to the performance management of network supported sites aids consistent delivery of your study to time and target.

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Globally, the median time to set up a complex study is 13–101 weeks; in the UK, it is currently 28 weeks. The NIHR’s study support service operates throughout the study process, helping with issues of feasibility, commercial costing templates, capability and capacity, model agreements and study management. In 2016/17, the NIHR helped improve

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\(^{10}\) [http://www.io.nih.ac.uk/about-us/]
study set-up and delivery with: 99% of NHS trusts supporting opportunities for people to actively participate in clinical research; 79% of NHS trusts recruited to commercial contract studies; and a median of 20 days to achieve NHS permission. The Network continued to demonstrate that the UK is internationally competitive in speed of study set-up by recruiting 24 global and four European first patients into studies in 2016/17. Two examples of NIHR CRN support for MedTech studies are now given:

Case study 1: Novian Health

Novian Health is a US-based medical device manufacturer, it completed enrollment into their multicenter, international, clinical trial to evaluate the treatment of small breast cancers with Novilase® laser ablation (Br-002) in 2015. “This was our first UK trial and working with the NIHR Clinical Research Network enabled us to hit the ground running in the UK. From quick adoption of the trial into their research portfolio and identifying interested investigators and sites within NHS, to ongoing monitoring of enrolment against performance objectives, we felt like we had a partner who was genuinely interested in a successful outcome. We were pleased to be able to evaluate Novilase laser ablation for the future benefit of NHS patients, appreciate the contributions of all staff and participating subjects, and in particular the NHS team in Bristol for being the lead recruiters in this trial. We look forward to working with NIHR Clinical Research Network in the future.”
Gene Bajorinas, Novian Health’s Vice President of Operations

Case study 2: PneumRx

PneumRx is a US-based company focused on the development of innovative minimally-invasive products to meet unmet needs in pulmonary medicine. Their flagship product is the RePneu endobronchial coil - an implantable device that improves lung function and quality of life in emphysema patients. A limited number of NHS Trusts have started using coils in the UK. The aim of the phase IV Lung Volume Reduction Coil study is to observe those patients and gather evidence of the benefits of endobronchial coil implantation to build a case for the coils being made more widely available to NHS patients. “This study is the first time our company have been involved with the Clinical Research Network. We were advised that getting the study accepted on the Clinical Research Network Portfolio would be a good way to raise awareness in the UK of coil technology and its benefits for patients. The Network as a whole has advised and provided support for ethics approvals as well as advising on the set-up of the study. And we’ve also used tools such as the costing template to help us get up and running.”
Mark Chambers, PneumRx’s Sales Manager for the UK and Ireland
Accelerating adoption of MedTech

System-wide uptake of a new medical technology requiring a robust evidence base of both clinical benefit and economic impact. Industry reports a number of existing barriers to innovation in the NHS, including difficulty in engaging with key individuals, institutional bureaucracy and a culture of “My IP = My Money”. Solutions need to include educating healthcare workers about innovation and medical entrepreneurship, better integration of innovation into clinical practice, and developing novel models of organising innovation.

Case studies: the good, the bad and the difficult

The good: pulse oximetry

Early oximeters led to the development of non-invasive pulse oximeters with acceptable precision over a clinically useful range, little drift and not requiring recalibration. Performance standards have been set although, there may be problems with misinterpretation;

Future developments include signal extraction technology; Hb, CO, MetHb monitoring; pulse variability index and wearable technology. Current pulse oximeters can be purchased inexpensively by the public.
The Bad: Gastrointestinal tonometry

"Maintaining the perfusion of critical organs is an accepted goal of critical care. Given that the blood supply of the GI tract is disproportionately reduced compared to other organs during life-threatening events such as haemorrhage, measures of gut blood supply would appear to be of clinical value. Gastric tonometry - the measurement of the partial pressure of CO2 in the gastric lumen - provides an indirect measure of GI tract perfusion when compared with arterial levels of CO2.

At a "State of the Art" meeting in 1998, "the panel agreed that currently the most viable method of reliably measuring GI luminal CO2 levels in the clinical setting is by using automated air tonometry (The Tonocap, Datex-Ohmeda, Instrumentarium, Helsinki, Finland) - a semi-continuous method of sampling gastric balloon air with infrared measurement of PCO2" (Chapman et al, Intensive Care Medicine 2000, Volume 26, Issue 5, pp 613–622).

However, since then, Gastric tonometry has not been widely adopted in clinical practice, despite the findings of a recent systematic review and meta-analysis which noted that "In critical care patients, gastric tonometry guided therapy can reduce total mortality" (Zhang et al. Critical Care (2015) 19:22). On reflection, there are probably two main reasons for the limited clinical deployment of GI tonometry (Mythen Critical Care (2015) 19:172);
The difficult: cardiac output monitoring

Using an oesophageal Doppler monitoring (ODM) system, central blood flow can be directly measured and monitored. Full implementation of ODM was listed as one of the 2011 Innovation Health and Wealth reports six high impact innovations to be implemented at pace and scale across the NHS. A number of studies have found the Deltex CardioQ-ODM provides statistically significant reduction in numbers of complications and length of stay. A NICE evaluation found this evidence supported the use of the CardioQ-ODM in the NHS to guide fluid administration via stroke volume optimisation during surgery and provided a cost saving per patient of over £1000 compared to alternative approaches (NICE MTG3: CardioQ-ODM oesophageal Doppler monitor). However, while use rose in 2012/2013, loss of CQUIN (Commissioning for Quality and Innovation) pre-qualification in January 2014 led to a decrease in its use.

What was the problem? Not all of the trials had statistically significant positive results. A recent, multi-centre, 450 patient trial showed a 72% reduction in complications, a reduction in hospital stay by 2 days and a reduction in post-surgical complications (Goal directed hemodynamic therapy decreases postoperative complications. Results from a multicenter randomised controlled trial. Ripolles-Melchior et al. EJA Vol 33, e-supplement 54, June 2016). Based on cost savings at the point of care, ODM is over 12 times more effective than is needed to pay for itself (Deltex Medical analysis). On a Quality of Life Year (QALY) basis, the UK will pay £25,000 for 1 QALY gained (The NICE cost-effectiveness threshold: what it is and what that means. McCabe et al. Pharmacoeconomics, 2008;26(9):733-744). Given that post-operative surgical complications are associated with an average reduction in life expectancy of 7 years, to be cost-effective, ODM would need to avoid a complication in 1 in 2,333 patients. (Determinants of Long-Term Survival After Major Surgery and the Adverse Effect of Postoperative Complications. Khuri et al. Annals of Surgery, 242,3, 2015. Deltex Medical analysis). A meta-analysis suggested that with ODM a complication is avoided in 1 in 7 patients, making it 333 times more effective than would be needed to meet the QALY criterion. (Intraoperative Fluid Management technologies and patient outcomes: a meta-analysis. Murrell C. www.deltexmedical.com. Deltex Medical analysis).
One way to help accelerate the adoption may be through social enterprises that combine community goals (e.g. a social or environmental mission) with corporate discipline. This can be achieved through a Community Interest Company (CIC), which uses profits and/or assets for the public good.

The Bloomsbury Innovation Group is one such example.

### Bloomsbury Innovation Group
A social enterprise (UK community interest company) owned by a charity (Special Trustees of University College Hospital NHS Trust). BIG comprises a core team of inventors and clinical innovators with a proven track record in medical device design. The aim is to remove the focus on maximising profit and protecting IP and focus instead on maximising benefit and minimising costs. BIG currently has six innovative devices in development including a pre-op carbohydrate drink, a video-laryngoscope and a face-mask.

A professional initiative to promote technology evaluation is the Royal College of Surgeons (RCS)/NIHR STEP (Surgical Technology Evaluation Portal). STEP is helping optimise the surgical technology evaluation pathway by creating a portal for industry and enabling evaluation through NIHR infrastructure, research teams, service delivery evaluation and clinical practitioners. The aims are to establish one common and visible portal by linking innovators to clinicians and researchers, providing access to a multidisciplinary team of specialist clinicians and researchers and combining the strengths of RCS surgeons and relevant NIHR infrastructure.

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11 [http://www.bloomsburyinnovation.com](http://www.bloomsburyinnovation.com)

The **STEP Steering Committee**\(^\text{13}\) comprises representatives from the NIHR; Department of Health, NICE, HTCs, MHRA, Association of British Healthcare Industries, the IDEAL (Idea, Development, Exploration, Assessment, Long-term follow up) Collaboration and Cancer Research UK as well as Anaesthetics, Surgical Speciality Level, Surgical Trials Unit and Clinical Research Initiative Steering Committee representatives. The Steering Committee meets on a quarterly basis to assess the outputs of the program and to give future direction. The aim is that by having a wide group of stakeholders any hurdles or barriers to technology assessment/evaluation and adoption can be identified early within the process. One of the key elements of the program is having Industry representation through relevant trade bodies.

**Next steps**

The key elements of a framework for the development of MedTech studies in the NHS include:

- Building on the Accelerated Access Review results for MedTech adoption including use of large academic health science centres as innovators.
- Improving the points of contact between NHS (clinicians, commissioners and managers) and industry (particularly SME sector) through a sustained programme of engagement, signposting and integration/joint working of cognate assets (e.g. AHSCs, AHSNs, NIHR infrastructure and NHS commissioners).
- Improving access for MedTech to robust, early-stage evaluations through HTCs, DECs and STEP.
- Capitalising on the breadth and depth of the NIHR CRN to deliver evaluation of implementation at scale and pace.
- Exploring different business models for SME product development and evaluation - for example, risk-sharing with public sector – that facilitate the development of innovative product.

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Relevant Resources

Guidance for industry

How to access support for product development
How to work with NIHR
How to work with Academic Health Science Networks

Other resources

Accelerated access review: Final Report, October 2016
Catapult, Innovate UK
MEDConNecT North: connecting NHS and Technology in North East and North Cumbria
NIHR: National Institute for Health Research
NIHR DEC in vitro diagnostics evidence generation pathway
NIHR Infrastructure
NIHR Study Support Service
NIHR i4i: Invention for Innovation
UK Strategy for Life Sciences, December 2011, Department for Business Innovation and Skills
Sepsis: recognition, diagnosis and early management, NICE guideline[NG51], July 2016

Website Links

1. NIHR Office for Clinical Research Infrastructure (NOCRI) https://www.nihr.ac.uk/about-us/how-we-are-managed/Managing-centres/nihr-office-for-clinical-research-infrastructure/
2. NIHR Clinical Research Network (CRN) https://www.nihr.ac.uk/about-us/how-we-are-managed/Managing-centres/crn/
3. MEDConNecT http://medconnectnorth.com/
4. CRN Key Statistics 16/17 https://www.nihr.ac.uk/about-us/how-we-are-managed/Managing-centres/crn/key-statistics.htm
5. NIHR Health Technology Collaboratives (HTCs) https://www.nihr.ac.uk/about-us/how-we-are-managed/Our-structure/infrastructure/healthcare-technology-co-operatives.htm
7. NIHR DEC initiative is the in vitro diagnostics evidence generation pathway https://www.nihr.ac.uk/life-sciences-
8. NIHR platform for medical technology and in-vitro diagnostics (MICs)  

9. NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs)  

10. NIHR Innovation Observatory (NIHRIO)  http://www.io.nihr.ac.uk/about-us/


12. Royal College of Surgeons (RCS)/NIHR STEP (Surgical Technology Evaluation Portal)  


Glossary

**ABHI:** Association of British Healthcare Industries  
**AHSCs:** Academic Health Service Centres  
**AHSNs:** Academic Health Science Networks  
**CLAHRCs:** Collaborations for Leadership in Applied Health Research and Care  
**DECs:** Diagnostic Evidence Co-operatives  
**HTCs:** Healthcare Technology Co-operatives  
**LCRN:** Local Clinical Research Network  
**NCRI:** National Cancer Research Institute  
**NICE:** National Institute for Health and Care Excellence  
**NIHR CRN:** Clinical Research Network  
**NOCRI:** NIHR Office for Clinical Research Infrastructure  
**RCS:** Royal College of Surgeons  
**STEP:** Surgical Technology Evaluation Portal
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Details of other declarations of interests are available through cognate Royal Colleges.