INTEGRATED CARE Supporting the vital role of boundaryspanning physician researchers in the advancement of medical innovation

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A wide range of stakeholders recognise that physicians play a vital role in medical innovation and, in particular, the importance of boundary-spanning engagement between physicians and industry in clinical research. While UK physicians are keen to take part in research, this article draws on a range of literature to identify apparent and anticipated challenges that discourage or prevent crosssector engagement by physician researchers. To encourage areater interaction and exploration of associated support mechanisms, we present a full spectrum of engagement modes, funding opportunities and illustrative initiatives, showing how different stakeholders (from government institutions, charities, professional bodies and industry) can contribute to improving the engagement of physicians in boundary spanning research. We emphasise the importance of mutual understanding, trust and commonly shared practices, as well as adequate resources, to encourage these vital interactions.

KEYWORDS: physician researcher, medical innovation, boundaryspanning, research collaboration

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Introduction

Clinical research underpins a wide range of innovations including the discovery of new drug classes, and the development of novel diagnostics and medical devices, which generally rely on the close interaction of physicians and industry. The fruits of such engagement include innovations in diagnostic imaging technologies, such as ultrasound and magnetic resonance imaging (MRI), endoscopes, intra-ocular lenses and coronary angioplasty. Moreover, systematic quantitative analysis of

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patent licensing practice in medical innovation supports the view that inventions of commercial interest originate in the clinic more often than they do in the lab, for example, through clinical observations that suggest new uses for drugs already on the market 1.6

Cross-sectoral engagement activities spanning public healthcare and industry may take a wide range of forms, such as physicians providing ad hoc advice, consultancy, contract research or participation in collaborative research.⁷ A key ingredient in the latter may be that physicians can provide industry partners with unique access to patients and tissue.⁶

Over recent years, facilitation of engagement with industry has become a more formalised role for hospitals, often with a government policy push to play a greater role in generating economic prosperity, just as universities were encouraged to take on this mission in addition to teaching and research. Indeed, the importance of cross-sector research engagement in hospitals is now seen as a vital part of the UK's 'competitive advantage' in the life sciences industry. Buoyed by the rapid and highly effective clinical research response to COVID-19, in March 2021, the UK government launched a new strategy to further encourage cross-sector collaboration between the NHS, academia, industry and government to drive clinical research. Yet, even before the adverse impact of COVID-19 on routine healthcare delivery, there had been a worrying decline in the capacity of NHS staff to engage in the research that underpins medical innovation.

Here, we explore some of the challenges now facing physician researchers in their efforts to engage in cross-sector research. The term 'physician researchers' is used here to include more than medical doctor (MD) – PhDs or clinician academics, emphasising the range of physicians who can help to span boundaries between healthcare, academia and industry, a vital role for many forms of medical innovation.

While the focus in this article is on physicians, it should also be emphasised that nurses, allied health professionals and non-clinical professional services staff also play essential roles in medical innovation and enhance the resilience of the research system. Clinical research and medical innovation are undoubtedly a team-based activity.

In order to encourage support for cross-sectoral clinical research, we highlight important themes from several distinct literatures. These include policy reports by key stakeholders (such as professional bodies and research funders) as well as

academic studies of medical innovation processes and, because the challenges of supporting cross-sector research engagement are not unique to medicine, we also draw on insights from studies of cross-sectoral collaboration by academic scientists beyond medicine. While many physicians are not academics (and the academics surveyed in the literature we draw on are generally not physicians), we suggest the research reviewed here nevertheless identifies relevant issues, some of which remain to be formally studied in populations of physicians working in healthcare systems in the UK or elsewhere.

We begin by exploring barriers to physicians' engagement in research, before focusing more specifically on the challenges of cross-sectoral research engagement. We then discuss some illustrative initiatives that aim to support cross-sector research involving physicians, drawing on the perspective of one of the world's most active industrial partners of clinical researchers, GlaxoSmithKline. While the initiatives discussed in the latter part of this article do not address the full range of challenges facing physician researchers, these illuminate many existing pathways for cross-sector engagement.

An appetite for research

Surveys in recent years show that most responding NHS physicians are keen to engage in research, including those without formal research appointments. ^{12,13} Of those already undertaking or interested in research, a majority identify motivations such as intellectual stimulation, benefits to patient care, up-skilling and adding variety to their work, while a majority already engaged in research suggest that this experience makes them better doctors. ¹² Indeed, this view is supported by evidence that clinical care is better in organisations that are research active. ¹⁴ It is now a major policy priority to increase NHS engagement in research. ¹⁵ Yet, while the numbers of consultants and general practitioners in the UK has expanded over time, the proportion of physicians engaged as clinical academics has been in a long and sustained decline. ¹⁰

Competing priorities

Insufficient time is one of the main barriers preventing physicians from engaging in research. ^{12,13} In a pre-Covid Royal College of Physicians (RCP) census, NHS consultants estimated that they work around 10% more hours than they were contracted to in order to meet their clinical duties. ¹⁶ In another RCP survey, two-thirds of responding physicians agreed that having dedicated time for research would be welcome. ¹³

An underlying problem here is the demand of competing roles, which require physicians to become 'hybrids' with duties and responsibilities driven by different 'institutional logics' and associated incentives. ^{17–19} Physicians are expected to combine the roles of healthcare provider, administrator and teacher (and, still at times, student too), while physician researchers may also feel they need to be collaborators, authors, project managers and even entrepreneurs.

Hospitals may not fully align the requirements that competing logics bring, nor ease resulting tensions, even when supporting translational research and entrepreneurial activities are seen as part of their mission. Indeed, a lack of research culture in hospital trusts is often cited as a barrier to research involvement by physicians. Difficulties can lead to physicians' resistance

and retreat.⁸ If it is too challenging for individuals to undertake multiple intense roles, choices are made between them.
Collaboration offers a solution to share the burden of research, yet time is also required for such engagement.²⁰ Inescapably, there is a need for more resource to address this challenge, however, more also needs to be done by trusts and funders, and the NHS more broadly, to facilitate involvement in research through a variety of mechanisms.^{10,13}

Access to research training

Research can seem a daunting activity for many, who may fear that they lack the skills to participate. This concern is highlighted by physicians responding to an RCP survey, with women and those from ethnic minority backgrounds more frequently feeling less able to contribute to research due to a lack of skills. Mentoring schemes may have an important role to play in addressing these concerns, but most physicians, including the vast majority of early-career physicians, report being unaware of how to access mentoring opportunities, suggesting important action is needed here by NHS employers. A range of research training opportunities are available to physicians at different career stages but these also could benefit from further promotion.

Access to funding

Funding can buy time for physicians to undertake research. Indeed, the National Institute for Health Research (NIHR) was established precisely to ensure ring-fencing of resources, including time, for research. In England, the NIHR Clinical Research Network ensures a research backbone exists in the NHS to provide support to clinical studies covering the whole country and major specialties. This enables thousands of studies to take place each year, independent of the care budget. A broad array of funders also provide grants for collaborative research and fellowships that are available to clinicians (Table 1). Yet, even the processes for applying for research time, as part of a clinician's 'job plan' or through funding bids, are seen by the target audience as burdensome.

Provision of core funding for physicians' research time, as provided by NIHR through the local Clinical Research Networks, is an important starting point to ensure practitioners have some time to conduct research, although this resource is spread thinly.²⁴ Successful bids for additional funding are therefore also important to buy-out time for research. However, this access may be limited due to physicians' available time to write grants, creating a 'chicken and egg problem'. Funders can help to address this, for example NIHR provides an advice service to aid access to funding for clinicians.²⁵ Growth in funding for translational research has also supported an increase in clinical research in the UK. However, the accessibility of these funds for many may be limited in practice; for example, there is some evidence from the USA that suggests MD-PhDs and PhDs have higher grant success than MDs when it comes to competitive bidding.²⁶ A possible source of advantage for physicians may come from industry, as some evidence suggests that having a commercial partner boosts chances of grant success. ^{27,28} Over a third of Medical Research Council (MRC) translational research awards involve an industrial partner, with the associated projects almost twice as likely to gain follow-on-funding compared with projects without industry partners.²⁹ Such collaborations have also led to a better

Table 1. Research PhDs and fellowships for physicians				
Founder	Scheme	Description	Webpage	
MRC and Wellcome Trust	Clinical Research Training Fellowship (CRTF)	2 to 4 years funding; salary and expenses provided	https://mrc.ukri.org/skills-careers/ fellowships/clinical-fellowships/clinical- research-training-fellowship-crtf	
MRC and various founders	Jointly-Funded Clinical Research Training Fellowship	Same type of funding as CRTF but in different areas of research	https://mrc.ukri.org/skills-careers/ fellowships/clinical-fellowships/jointly- funded-clinical-research-training- fellowship	
Wellcome Trust	PhD Training Fellowship for Clinicians	New funding strategy in 2021: current offer: salary and expenses are covered for 3 years; programme open for different areas of research and at different universities and hospitals	https://wellcome.org/grant- funding/schemes/clinical-phd- programmeshttps://wellcome.org/ about-us/strategy/how-funding- changing	
MRC and University of Liverpool and industrial partners	North West England MRC Fellowship Scheme in Clinical Pharmacology and Therapeutics	3 years funding; salary and expenses provided	www.liverpool.ac.uk/north-west- england-mrc-fellowship-cpt/ recruitment	
Cancer Research UK	Clinician Scientist Fellowship	5 years; salary, equipment and expenses provided	www.cancerresearchuk.org/funding- for-researchers/our-funding-schemes/ clinician-scientist-fellowship	
Cancer Research UK	Clinical Trial Fellowship Award	3 years; salary, equipment and expenses provided	www.cancerresearchuk.org/funding- for-researchers/our-funding-schemes/ clinical-trial-fellowship-award	
NIHR	Doctoral and Advanced Fellowship	Full time (2 to 5 years) and part time (2 to 10 years); between 80% to 100% of salary, expenses and equipment covered	www.nihr.ac.uk/explore-nihr/academy- programmes/fellowship-programme. htmwww.nihr.ac.uk/documents/ nihr-doctoral-and-advanced- fellowships-round-5-guidance-notes- october-2020/25915	
UK Research and Innovation	Innovation Scholars	Salary and expenses provided; possibility to work during the secondment on a research project in a laboratory in a pharmaceutical, biotech, devices, biomedical engineering or diagnostics company	www.ukri.org/opportunity/innovation- scholars-secondments-biomedical- sciences	
British Heart Foundation	Clinical Research Training Fellowship	3 years; salary and expenses provided	www.bhf.org.uk/for-professionals/ information-for-researchers/what- we-fund/clinical-research-training- fellowships	
The Academy of Medical Sciences	Clinician Scientist Fellowship	5 years; salary and expenses provided	https://acmedsci.ac.uk/grants-and- schemes/grant-schemes/csf	
The Academy of Medical Sciences	Funding for postdoctoral clinical researchers	Various grants and funding schemes available	https://acmedsci.ac.uk/grants-and- schemes/whats-available-to-me/ postdoctoral-clinical-researchers	
UK Research and Innovation	Future Leaders Fellowship	4 to 7 years funding for ambitious research/innovation programmes; focusing on early career researchers/professionals wishing to transition toward more research	www.ukri.org/our-work/developing- people-and-skills/future-leaders- fellowships/what-are-future-leaders- fellowships	

Freedom and credibility

Physician researchers may be wary of industrial partners limiting their intellectual freedom; for example, drawing on evidence beyond medicine, a study of German academic scientists suggests those working with industry may delay publication and become more secretive. ^{30,31} Yet, evidence from the USA shows that academics collaborating with industry tend to be more collaborative across all interaction types, although, perhaps high levels of industry interaction crowd out other forms of collaboration. ³² Certainly, the fear of limits to freedom and harms to scientific credibility have deterred engagement of Italian and Spanish scientists with firms. ^{33,34} However, scientific publications with both academic and industry co-authors tend to have higher citations than those of academics alone, suggesting that, in fact, such collaborative work is more widely acknowledged. ³⁵

In the UK, where cross-sector collaboration is a major policy focus, the introduction of published impact cases as part of the Research Excellence Framework has encouraged partners to disclose the influence of academic research and put a spotlight on successful collaboration. ³⁶ Beyond policy levers, peer effects may also have a positive influence. Studies show that academic scientists are more likely to collaborate with industry following prior engagement by their co-authors and contacts, particularly where senior staff are role models for junior staff, and where industry links involve prior contacts, such as former students. ^{37–39}

Unethical practices

There is no hiding the fact that the pharmaceutical industry has historically engaged in well documented unethical practices, such as failing to publish the results of clinical studies with unfavourable results, ghost-writing scientific publications and paying physicians to influence their prescribing decisions. ^{40,41} This behaviour may generate suspicion and unwillingness to engage with industry. A resulting danger is that collaborative opportunities are missed, with patients and society less well served by medical research as a result. Progress has been made in recent years to address published concerns, with results from commercially sponsored trials now more likely to be published than those without commercial involvement. ⁴² However, more can and should be done to ensure industry engagement centres on gaining knowledge rather than gaining influence. ⁴³

Inter-organisational friction

The organisation of research often requires considerable nurturing of collaboration across boundaries, particularly in biomedical research where teams may be composed of individuals from diverse organisations, institutions and backgrounds.¹⁷

Survey evidence from UK firms engaged in academic collaboration (again, not specific to medicine) suggest commonly experienced barriers relate mainly to differences in research orientation and difficulties around transactions. ⁴⁴ Differences in orientation include a tendency for academics to be more interested in research than application, and to work to longer timeframes. Both industry and academic partners also often lack understanding of each other's expectations and working

practices. Moreover, the formalisation of knowledge transfer and commercialisation activities in academic institutions can perturb traditional collaborations characterised by 'informal reciprocity and exchange'. ⁴⁴ Transactional barriers may stem from the unrealistic expectations (or absence) of industrial liaison officers, and conflicts over intellectual property terms and conditions, as well as difficulties with institutional regulations (including from funders). Surveyed academics working with industry report transactional barriers are those most commonly encountered. ²⁸ These barriers can be expected to reduce as interpersonal trust develops between partners, over the long term and after repeat interactions through a range of channels, supported by mutual understanding built up through face-to-face meetings and interpersonal relationships. ⁴⁴ Yet, this may not be helpful or encouraging for those experiencing difficulties in the short term.

Diversity and participation

In medicine, research opportunities remain less available to women, ethnic minorities and those working in non-university hospitals, particularly those in rural locations. 13 Naturally then, clinical researcher engagement with industry may also require efforts to reach beyond the usual suspects and places to engage demographics that have previously found cross-sectoral engagement opportunities more difficult to access, and to find untapped reserves of expertise. Studies of the demographic characteristics of academics engaging beyond universities are more common than those in medicine, and so are relied on here. This research shows that, in the UK, male academics are significantly more likely to engage with industry, but also that institutional policies can have strong equalising effects on this trend. 45 Mid-career academics are also more engaged than those in early and late career. 46 Academics born or trained domestically (those with British PhDs) tend to collaborate more with domestic firms than those foreign born or trained internationally, but this weak effect diminishes over time, and both groups engage more intra-nationally than internationally.46

Poorly designed policy

Much remains unknown about which policies effectively promote cross-sectoral engagement and even less is known about policies to improve hospitals' innovation-related functions. The little that is known suggests interventions can perform poorly. Perhaps the most supported finding is that hospitals engaged in teaching tend to be more supportive of innovation, although how this broad category relates to particular forms of collaboration is unknown. One observation from studies of academic engagement is that policies stimulating commercialisation (patenting and spin-outs) may draw academics away from other forms of engagement and some institutional controls may also dissuade academic from engagement. 48,49 Further research around suitable policy responses and their effects would provide a more solid basis for interventions.

Working with industry

Pharmaceutical firms have long worked with and employed physician researchers, including at senior levels, and greatly benefit from their experience. The authors have most familiarly with the organisation of research and development (R&D) at

	Description	Notes
Collaborative mode		
MD-PhDs	An early career physician undertakes an intercalated PhD	May be truncated (2 years), sometimes co-funded with charity/research council
Clinical fellowships	Internally funded by industry or externally funded (or mixed)	May be expensive for the industry partner
Funded collaborations	Company funds research solely or shares project costs with charity or research council	Intellectual contribution from both industry and academic parties
Material transfer	Company provides a compound or biological tool for external research	May be an investigator-sponsored study or a company-sponsored study; intellectual property agreements will differ accordingly
Funded collaboration and material transfer	Company provides funding and materials, and can also provide personnel time	May involve use of specialist equipment or tools not available in hospital setting
Visiting scientist positions	Sabbaticals to learn about industry processes but also to provide domain expertise that benefits the host company	Salary buy-outs possible and provision of access to resources (typically over 3–12 months)
Fee for service mode		
Consultancy	Physician provides advice on pre-clinical and/or clinical projects	One-way flow of information from physician to company
Contract research	Clinician undertakes a service which may or may not result in publications	The primary driver is financial and may not necessarily expand the science base

GlaxoSmithKline (GSK), where the drug 'discovery performance units' have embedded physicians, and occasionally have physicians as group leads. Some have dual posts (in the pharmaceutical industry and in the NHS) so as to maintain their connection to and focus on patient care. Some had their first experience of industry working on collaborative projects with GSK.

It is clear that, although cross-sector engagement is highly valued, the challenges of working across sectors to advance medical innovation are very real. Sustained and often coordinated efforts by research councils, charities, industry, and professional and trade associations have sought to support engagement. A range of initiatives are presented here to illustrate possible models for mechanisms to spur collaboration between physicians, academia and industry. Several of these examples are initiatives that the authors have close knowledge of. These cover many (but not all) of the engagement modes introduced in Table 2. It is not for the authors to evaluate the success of these initiatives (indeed, some were more recently established than others). Instead, we set out key features of a number of promising initiatives that might be considered for adaption and use elsewhere, or sought out by those to whom they may be of interest.

Building familiarity and understanding

Clinical research is complex and specialised. Joint initiatives by a range of professional and trade bodies have established dedicated efforts to promote careers in key specialisms where shortages of practitioners threaten to narrow the capacity for R&D across the country. The Clinical Pharmacology Skills Alliance (CPSA) was formed by the Association of the British Pharmaceutical Industry (ABPI), the British Pharmacological Society (BPS), the Faculty of

Pharmaceutical Medicine (FPM) and Health Education England (HEE) to support the growth of clinical pharmacology as a medical specialism through promoting awareness and training. ⁵⁰ The CPSA is driving progress towards the British Pharmacological Society's target of 150 active consultants in the UK by 2025 (there were 100 in 2020). ⁵⁰

Ensuring that physicians understand the processes and demands of commercial R&D and know how to ethically engage with industry helps to demystify the industry, which may be a crucial step in facilitating engagement. A joint project between Brighton and Sussex Medical School (BSMS), ABPI and FPM has led to the piloting of a special study module that addresses these themes as part of the undergraduate medical curriculum. Adopted by BSMS in 2020, it is envisaged that other medical schools will follow suit.

Similarly, in 2019 the Academy of Medical Sciences established the Future Leaders in Innovation, Enterprise and Research (FLIER) programme to bring together people prepared to grapple with healthcare challenges by working across boundaries and disciplines (Fig 1). Through a series of events, participants from a range of professions, including academics, clinicians and industry executives, share their perspectives, build their understanding of others and begin to break down the barriers that make collaboration difficult. At the same time, participants gain the practical knowledge needed to address challenges that require cross-sector collaboration. Cross-sector exchanges also provide key opportunities to signal between organisations about changing needs.

The programme recruits a new cohort of FLIERs annually and equips these emerging leaders with skills to help solve important health challenges and enables them to seize opportunities afforded by new discoveries in science, technology and medicine.



Fig 1. Future Leaders in Innovation, Enterprise and Research (FLIER) programme first cohort. Reproduced with permission from Big T Images and The Academy of Medical Sciences.

Robust governance and shared standards

Robust governance and use of shared standards are a cornerstone of collaboration across sectors in science. In response to prior failings, companies have committed to publishing all clinical trial results, although many historical trials underpinning widely used medicines remain to be published.⁵¹ Scientific and medical journals have also introduced more stringent authorship guidelines and transparency requirements around research funding. Research institutions and professional bodies have introduced declarations of conflicts of interest to protect against the 'corrosive public scepticism' that bad practice results in. 52 Registries recording engagements are one way to improve transparency; for example, the European Federation of Pharmaceutical Industries and Associations require its members to disclose payments to healthcare professionals, while EU legislation requires disclosure to the European Medicines Agency of collaborators involved in clinical trials. 53,54

The need for greater transparency extends to industry's collaborators too, as companies seek higher standards of data integrity and more reproducible research findings. The opportunities provided by big data and new digital platforms can only be exploited if collaborators share understanding of these tools and work to shared standards. Here, the UK Reproducibility Network provides an example of a consortium leading the embedding of best practice. 55

Modes of collaboration

Industry has long invested in a range of different collaborative modes to access expertise and clinical resources. A prominent example is GSK's Clinical Unit in Cambridge (CUC) founded in 1999 in a purpose-built facility at Addenbrooke's Hospital to conduct experimental medicine studies. CUC has specialist 'phase 1 unit' accreditation from the Medicines and Healthcare products Regulatory Agency and a dedicated on-site biomarker laboratory to conduct experiments on fresh samples to yield maximum pharmacodynamic information from first-in-human clinical trials.

CUC enables GSK to access medical and scientific expertise from the world class research community co-located at the

Addenbrooke's biomedical campus to recruit patients to studies through the hospital and to access databases such as NIHR Bioresource

While the CUC studies are led by GSK, the company's clinic-ready asset portfolio is also made available for experimental medicine studies led by independent investigators, through the Eminent programme, an example of a public–private co-funding scheme for clinical research. In Eminent, the MRC provides funding, matched by GSK, for external investigators based at Cambridge, Imperial College London, Glasgow, Newcastle and University College London to study candidate drugs and disease mechanisms in underserved disease areas. Promising indications can be taken forward by GSK, for example, as in the recent phase III trial for otilimab for hyper-inflammation associated with COVID-19. 56

Many other grant-funded mechanisms can be used to support those hoping to collaborate with industry, from PhD studentships and fellowships to collaborative projects (Table 1). Crucially these can provide an opportunity for physicians to buy-out time to spend on research or to bring in collaborators to share the work. Often the industry partner can provide project management expertise to support busy clinicians. The north-west England MRC fellowship scheme is one example where universities (Liverpool and Manchester) with basic and clinical pharmacology expertise work with several pharmaceutical firms (Lilly, Novartis, Roche and UCB Pharma) to provide opportunities for medically trained fellows to work in drug development.⁵⁷

Developing a culture of openness to external scientists has been a trend in the pharmaceutical industry. In 2015, GSK established the Immunology Catalyst to attract leading scientists, including physicians, to spend up to 3 years (at 20–80% full time equivalents) on sabbatical working side-by-side in the lab with the company's own scientists at their Stevenage R&D centre. There, they have unrestricted access to the facilities to run their own studies and keep any intellectual property they develop (where these are not associated to GSK proprietary assets).

This research programme has an external immunology board composed of world-renowned figures in immunology who advise the network. An associated immunology fund supports external visitors to further their research at GSK, including reimbursement for salary costs to their home institutions from GSK, as well as the costs of associated researchers that may need to be hired or brought along.

Participants learn first-hand how industry works, improve their understanding of the drug R&D process, make contacts and advance their academic research or provide them with experience to gain employment in the private sector. GSK scientists benefit from interaction with leading thinkers in immunology who appraise their work. A bi-annual 'immunology summit' at GSK's R&D centre in Stevenage allows the network to share its progress with internal scientists and the wider international scientific community (Fig 2).

Conclusion

Medical innovation relies on boundary-spanning physician researchers. These individuals can collaborate with industry more easily when there is mutual understanding, trust and commonly shared practices. These stem from engagement that allows the exchange of ideas and materials, and the movement of people across sectors. Communication of the benefits of engagement with industry needs to be accompanied by efforts to address the



Fig 2. Physician researchers meet at an 'immunology summit' at GlaxoSmithKline research and development centre in Stevenage.
Reproduced with permission from GlaxoSmithKline.

challenges highlighted here that need to be overcome in order for physician researchers to engage across sectors. Equally, there are many mechanisms that can help broaden the accessibility and appeal of cross-sector research, and all stakeholders need to work to expand the provision of mechanisms that demonstrate their effectiveness, as well as communicating how to make use of these. Of course, the utility of these mechanisms will vary according to local circumstances and must be kept under review, both regionally and nationally to ensure suitable levels of accessibility.

Cross-sector engagement of physician researchers may be highly valued, but the physicians' attention and time is hard won. Certainly, co-funding schemes drawing together public and private funding, widely used in the UK, have been effective at providing a platform for cross-sectoral collaborations. Yet an obvious conclusion is that without adequate resourcing through the NHS and research funding bodies, it will be difficult for these vital collaborations to flourish and to ultimately provide benefit to patients.

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