Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

data representativeness, with the possibility to share data internationally with appropriate safeguards; and (6) facilitation of secure data exchange outside the EU or European Economic Area for public health and academic research purposes.

Building on previous initiatives that contribute to a higher degree of harmonisation,[2,3] developing unambiguous implementation guidelines for member states on research activities could be regarded favourably, not only by paediatric haematology and oncology professionals, but across all fields of academic research. The European Commission proposal for the creation of a European Health Data Space holds further potential to support scientific research and envisages a common scheme for research projects conducted in multiple EU member states, as suggested by the European Data Protection Board.[4] SIOP Europe encourages the adoption of such an approach as highlighted in its Strategic Plan Update 2021–26, which states that sharing, integrating, and analysing extensive datasets as one is central to advancing childhood cancer research.[5]

Although the GDPR acts as an essential tool for protecting EU citizens' personal health data, the recommendations stemming from the SIOP Europe survey on its impact on childhood cancer research in Europe strive to improve and simplify the sharing environment for data and biological samples to facilitate research activities across all fields of research. To achieve long-term progress and foster effective cross-border data sharing, further concerted efforts are needed at both the EU and member state levels. SIOP Europe will engage in continued dialogue with relevant EU bodies, including the European Data Protection Board, to promote a harmonised implementation of the GDPR within and across EU member states for the benefit of health research.

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Importance of clinical research for the UK's 10-year cancer plan

The ambition of the UK Government's 10-year cancer plan consultation document to transform cancer outcomes is highly welcome.[1] This consultation must reflect on the extraordinary role played by the UK research community in responding to COVID-19—a response enabled by clinical research delivery infrastructure embedded within the National Health Service (NHS), which allowed rapid clinical evaluation of novel treatments and vaccines to save and transform lives. This unique national research delivery capability is the legacy of more than two decades of national clinical research networks, with co-operation between government agencies, charitable funders, and many others. This national capability started in cancer with the inception of the National Cancer Research Network and the National Cancer Research Institute (NCRI) in 2001. Now, through the National Institute for Health and Care Research (NIHR) Clinical Research Network (CRN), it extends across the full spectrum of health and social care. Cancer outcomes have been

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radically improved during this time, but further gains will require reinvigoration and realignment of our research capability at multiple levels, starting with the health-care workforce.

Driving large-scale research programmes requires major clinical leadership, time, and resources. The NCRI Research Groups and NIHR CRN Cancer Specialty Oversight Groups are established networks of expert clinicians, scientists, and consumers, ready to advise on key priorities and develop research proposals addressing them, whereas both the NIHR and medical royal colleges have initiatives to train and enthuse tomorrow's investigators and innovators. However, urgent attention is needed to maintain momentum, and support existing consultants, who, in the post-pandemic climate of a severely overstretched cancer workforce, face unprecedented service demands; time for research is scarce. National leaders applauding COVID-19 research programmes demand that research becomes integral with NHS service delivery.[2,3] To achieve this goal, research time must be embedded within consultant job plans. Furthermore, releasing highly trained staff to lead research requires funding to backfill service commitments. Clinical academic excellence must be valued and fairly rewarded, to avoid demoralisation and clinicians disengaging from research.

Screening, Prevention and Early Detection (SPED) research has perhaps the greatest potential to reduce our population's cancer mortality. Rapidly evolving SPED technologies need detailed evaluation through robust, large-scale prospective trials. National clinical initiatives, such as Targeted Lung Health Checks, Rapid Diagnostic Centres, and Community Diagnostic Hubs, are ideal platforms for such endeavours, exemplified by NIHR portfolio lung screening and biomarker research. Multicancer early detection tests, such as in the Galleri trial and related studies supported by NHS England and NIHR, are particularly attractive, but require rigorous analysis of many aspects of implementation, beyond simply assay performance.[4] The UK's research infrastructure is uniquely capable of rapidly recruiting large numbers of at-risk individuals across wide geographical and cultural strata. However, SPED research is predominantly a community endeavour, done outside acute hospital oncology and surgery departments, so requires new infrastructure distinct from existing resources, which instead focus primarily on patients already diagnosed with cancer. Stretched primary care services are poorly equipped to embrace research expansion that is crucial for SPED to flourish. This needs careful consideration with better resourcing, and primary and secondary care experts collaborating on optimal use of finite resources. In particular, systematic expansion of research infrastructure supporting screening, Rapid Diagnostic Centres, and Community Diagnostic Hubs should be mandated to host research as a matter of course.

Modern cancer drugs, which have transformed survival outcomes for some types of cancers, largely stem from laboratory discoveries associated with cancer biology, with effective partnership between academia and life sciences industries. In the UK, much of this early-phase research has been led by our Experimental Cancer Medicine Centre Network, which must be sustained and expanded if we are to retain the strong pharmaceutical industry relationships that exist, given international competition from EU member countries, the USA, and Australia, among others. NHS genomics services are developing rapidly, offering many benefits for precision medicine; however, our full research potential is often constrained by manpower, equipment, and commissioning arrangements, which are substantial barriers to attaining our full research capability. The current NHS genomics focus is necessarily on comparatively few genetic alterations associated with approved targeted cancer medicines—generation of far more extensive genetic information to signpost patients to trials of novel diagnostics and therapies must be developed and made readily accessible in real time through initiatives such as Our Future Health.

The NIHR portfolio contains more than 1300 cancer studies, with more than 800 actively recruiting. The burden on multiple elements of the NHS to undertake this research activity is not insignificant. Our resources are finite, so we need a manageable portfolio, but with sufficient breadth and variety to ensure that all patients who wish to engage with research can benefit from state-of-the art interventions. We must propagate the successes of the urgent public health COVID-19 studies and generate efficiencies in study setup and study design (eg, platform studies) if we are to become more cost-effective with our time and manpower. The new NIHR National Patient Recruitment Centres are generating successes by adopting single approval and

For more on **Our Future Health** see https://ourfuturehealth.org.uk

For the **NIHR Be Part of Research campaign** see https://bepartofresearch.nihr.ac.uk/

costing processes that need to be implemented across all NHS trusts. Regulatory and research governance processes, so risk averse that they restrict even access to anonymised patient data, require urgent revitalisation and risk-proportionate approaches.

Demand for access to new treatments is fierce, generating a substantial risk of new treatment adoption based on scarce early positive data, not borne out in subsequent phase 3 trials. The UK's robust evidence-based approach to evaluating new innovations gives an important opportunity to work with commercial partners to address health economic endpoints and prioritise cost-effective interventions. Our new proton beam radiotherapy centres in Manchester and London, combining traditional randomised trials and thorough Commissioning through Evaluation by NHS England, is already generating data likely to be internationally practice changing. Learning from this approach (ie, bringing health-care providers closer to our research community) and applying it to other expensive health-care technologies could become a key UK strength. For example, evidence-based practice in surgery has grown rapidly in the past decade, and remains a key treatment modality for many patients with cancer. Implementation of new surgical technologies or devices needs well governed processes if we are to avoid harm and adverse outcomes.[5]

Above all, we are mindful that substantial inequalities in access to routine health services and research participation were exacerbated by the COVID-19 pandemic. Patients with cancer in England, UK, deserve equitable access to clinical trial participation, evidenced transparently by NIHR and NHS England data collection systems. The NIHR Be Part of Research platform has huge potential to signpost patients and clinicians to clinical trials in real time, but needs substantial development to be truly effective. The NIHR Best Research for Best Health: The Next Chapter expects research to improve outcomes for diverse and underserved communities, addressing at-risk populations and promoting equity of access.[2]

Routinely collected real world health data must revolutionise research data curation. Despite impressive UK national datasets and IT capability, data remain disproportionately difficult to access. Flagship digital policy documents, such as those of The Health Foundation and Goldacre Review,[6] should be scrutinised for research opportunities, and recommendations implemented. The 10-year cancer plan must include investment in technologies to facilitate research within all services and in digital environments, with focus on keeping patients closer to home, using virtual interaction tools, remote consultations, and e-consent platforms.

UK cancer research has a strong track record in designing and delivering academically led studies investigating treatment de-escalation, reducing the burden of treatment on individual patients physically, emotionally, and financially, and on the health-care system, while maintaining best outcomes.[7–9] Such trials save health-care resources and are globally relevant. However, few countries can deliver such trials, which are rarely prioritised by pharmaceutical companies. Optimising use of high-cost cancer interventions through prospective studies depends on a strong programme of NIHR-led and NCRI-led research, underwritten by coordinated support from regulators, research funders, and cancer care commissioners. This unique strength of UK academia could be the focus of a specific Health Technology Assessment programme supported by NIHR and NHS funding. Much academic research developed in direct partnership with patient and public involvement includes important patient-centred outcomes focusing on quality, as much as quantity, of life. Our strong research programmes addressing end-of-life care and long-term survivorship issues are unique strengths affording great potential for the UK to be world-leading in these challenging areas of cancer care.

Health-care innovation and technological advances depend on important research infrastructure and translational research community resource. It is imperative to prioritise and properly resource all aspects of cancer research capacity, from bench to bedside, if we are to make substantial gains in cancer outcomes in the next decade. We call on the UK government and oncology research community to draw on these views to ensure a research-embedded 10-year cancer plan.

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Project Orbis: the UK experience after 1 year

On May 7, 2021, the UK medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), approved the tyrosine kinase inhibitor, osimertinib, for use as adjuvant treatment in EGFR-positive non-small-cell lung cancer (NSCLC).[1] This authorisation was notable, being the first UK regulatory filing to be completed through Project Orbis, a multinational oncology review programme, some 15 days before market authorisation in the EU.

Project Orbis was designed as a global collaborative regulatory review programme led by the US Food and Drug Administration (FDA) Oncology Center of Excellence, with the goal of accelerating regulatory approval of innovative cancer medicines among international partners, with a framework of coordinated regulatory submission and review.[2] The rationale was that leverage of regulatory partnership between international agencies has the potential to allow for faster submission, review, and approval of new innovative cancer therapies. A central principle of this global collaboration is that each regulator retains full independence regarding national approval decisions, and is not obliged to follow the actions of other partners. Project Orbis was launched in May, 2019, by the FDA with regulatory agencies from Australia (Therapeutic Goods Administration) and Canada (Health Canada); however, this collaboration has grown to include