SHELFORD GROUP SUBMISSION TO HOUSE OF LORDS SCIENCE AND TECHNOLOGY COMMITTEE ON LIFE SCIENCES STRATEGY AND SECTOR DEAL

Purpose of paper

1. The Government published its Industrial Strategy Green Paper for consultation on 23 January 2017.[1] It aims to cultivate the UK's world leading industries through 'sector deals'. Professor Sir John Bell published his report to the Government on the life sciences element of the Industrial Strategy on 30 August 2017.[2] We fully support that strategy, including its endorsement of the Accelerated Access Review,[3] and some of our member Chief Executives have contributed to its development. This paper discusses ways in which it can be taken forward to implementation through the anticipated sector deal for life sciences, with a particular focus on how major research institutions in the NHS can better work in partnership with academia and industry.

2. As some of the largest organisations and research centres in the NHS, the Shelford Group members aim to play a full and constructive role in the development and implementation of the life sciences sector deal.

3. This paper builds on discussions with policymakers and on input from Shelford Group Chief Executives, Medical Directors and Directors of Research, Academic Health Science Centres (AHSCs) and Biomedical Research Centres (BRCs). The key question we seek to address is how NHS organisations, working with our partners in academia and industry, can maximise our potential as engines for economic growth, as part of the sector deal for UK life sciences.

4. There are a number of recommendations below that we believe will support this aim. Our central recommendation is that, as part of the life sciences sector deal, the Government should establish a competitive process to designate and fund innovation hubs or clusters, which should be partnerships between leading NHS organisations, universities and the life sciences industry with a main aim to boost UK economic growth.

5. This paper discusses the key enablers for innovation hubs/clusters, a process for designation and potential outcomes. Where possible, they should build upon, integrate and catalyse the most innovative and successful of the existing structures, such as AHSCs, BRCs and Academic Health Science Networks (AHSNs). Some centres have already established overarching systems to pull these separate awards together into a single streamlined process aimed at improved healthcare and economic growth. Different options will be required in different part of the country and that should be encouraged.

6. The rigour of the competitions to designate major National Institute for Health Research (NIHR) infrastructure, such as BRCs, Clinical Research Facilities (CRFs) and MedTech and In vitro diagnostic Co-operatives (MICs), backed by a serious commitment to fund world leading research, provides important lessons to be learned and platforms that innovation hubs/clusters can build upon.

7. We believe there is potential for a step change in the way industry works with NHS clinicians and researchers to access patients and large datasets, develop new technologies and adopt innovations more efficiently and effectively. We seek a major shift towards greater collaboration between our globally recognised life sciences industry, universities and NHS. We see a renewed opportunity in the sector deal to foster the culture of collaboration and entrepreneurialism that is the hallmark of the leading innovation eco-systems around the world.

About the Shelford Group

8. The Shelford Group represents ten of the leading NHS multi-specialty academic healthcare centres in England:[4]

    - Cambridge University Hospitals NHS Foundation Trust
    - Central Manchester University Hospitals NHS Foundation Trust
    - Guy's and St Thomas' NHS Foundation Trust
    - Imperial College Healthcare NHS Trust
    - King's College London Hospital NHS Foundation Trust
    - Newcastle-upon-Tyne Hospitals NHS Foundation Trust
    - Oxford University Hospitals NHS Foundation Trust
    - Sheffield Teaching Hospitals NHS Foundation Trust
    - University College London Hospitals NHS Foundation Trust
    - University Hospitals Birmingham NHS Foundation Trust

9. We are distinguished by the size, complexity and quality of our organisations and services. We have a track record over many years of delivering excellent patient care, clinical research and professional education.

10. In aggregate, we provide high quality health services worth around £10bn p.a., which is equivalent to 10% of the NHS England budget and nearly 15% of all NHS providers. We treat many millions of patients each year across the full spectrum of clinical specialties.

11. We are national and international centres of research, education and innovation, providing some of the most complex and specialised healthcare in the world. One third of our aggregate income is for specialised services, many of which diagnose and treat rare diseases that are a particular focus for the life sciences industry.

12. We are NHS partners in all six of the nationally accredited AHSCs. All of our organisations are designated BRCs, accounting for over two-thirds of the available NIHR funding between them. We also host eight of the 13 NHS Genomic Medicine Centres in England, delivering the 100,000 Genome Project.

13. As a group, we aspire to provide system-wide leadership for the benefit of patients and the prosperity of the country. Our membership is confined to the English NHS, rather than being UK-wide.

Cultivating world leading sectors

14. We fully support the intention of the Industrial Strategy to cultivate world leading sectors, including life sciences. Previous attempts have led to some notable programmatic successes, but have failed to tackle fully the cultural barriers to a more synergistic set of arrangements between the NHS, our top universities and industry, especially where they are less well developed outside the 'Golden Triangle'. Despite the apparent advantage of being the largest single payer health system in the world, we are well aware that the NHS needs to play a much greater role, harnessing its access to tens of millions of patients, vital health data and a deep talent pool of clinician scientists.

15. Our ageing population, advances in medical technologies and the decade of austerity have put the NHS under increasing pressure. Whilst public support for the NHS remains strong, there is much debate about the most appropriate path for long term sustainability.[5] We see the life sciences sector deal as an important opportunity to reposition the NHS as a generator of workforce productivity, intellectual property and economic growth for the country, not just as a consumer of public expenditure as it is often perceived.

16. The major centres of research and innovation in the NHS need to embrace this agenda and are eager to do so. As Sir John Bell's strategy argues, we must help to convert the UK's strong competitive position in basic science through to translational research and commercialisation; a focus on the full innovation cycle which is currently lacking. We need to unlock the potential of new diagnostics and for research and development to benefit from the most comprehensive health records dataset in the world. In order for that to happen, there needs to be appropriate investment in infrastructure, skills development and culture change to fully triangulate the NHS, universities and industry. There is also a unique moment in time through Brexit to reconsider our national regulatory framework, from basic science through to implementation, to maximise efficiency and promote innovation.

17. Innovation will not happen at a uniform pace across the NHS or the country. We need a way to enable the most dynamic regional or sub-regional systems to forge ahead and to set the path for others to follow. That brings into focus the need to find the right balance between supporting systems with a long track record of success (incumbency) and targeted investment at major conurbations where there is both a need and opportunity for rapid economic growth (rebalancing).

Creating institutions to bring together sectors and places; driving growth across the whole country

18. A competitive process is essential to ensure that the designation of innovation hubs or clusters is robust and meritocratic. Examples of where this has been done successfully in recent years are the designation of AHSCs and BRCs. However, both of those processes have tended to favour the strongest incumbents of the Golden Triangle, either by designation or by volume of funding. Those three cities account for all but one of the AHSCs (Manchester being the other) and for 83% of the £816m allocated to BRCs over the next five years by the NIHR.[6]

19. It is essential that the life sciences sector deal both furthers the excellence of the Golden Triangle and more actively rebalances growth towards the country's other internationally recognised centres of research and innovation, situated in cities with a major need and opportunity for economic growth. There are a number of ways to support these twin aims, which will require some targeted rebalancing; for instance by designating national centres to lead on particular themes or gaps in our current national capabilities, such as Institutes of Technology;[7] and by the creation of inter-operable Digital Innovation Hubs or 'data lakes' that can enable research across traditional geographical boundaries.

20. Better regional development in research and innovation can also be supported by investment in infrastructure, such as science parks, transport and housing, or fiscal enablers, such as favourable local business rates, tax credits or VAT relief.

21. In that context, we make the following recommendations for a competitive bidding process to designate innovation hubs/clusters that build on our strongest research centres and that are geographically spread across the country:

- **Investment** – whilst we do not recommend a specific amount of investment, we would point out that the funding has to be sufficient to 'move the system' in the way that NIHR funding has for BRCs. Conversely, AHSCs and AHSNs have struggled to deliver their potential with very limited resources. We note that the Accelerated Access Review (AAR) suggested a specific fund of £4-8m each for research active tertiary hospitals that host AHSCs or BRCs as one component to implement and champion AAR pathways.[8] We were pleased that the recently published Life Sciences Strategy endorsed the AAR recommendations. Return on investment needs to be a key metric by which innovation hubs/clusters are judged. Investment needs to be seen in the context of the overall NHS funding situation, which is discussed below.

- **Build on existing institutions where possible** – it will be important to harness and integrate the best of existing structures, whilst providing the platform for renewal and innovation. Several centres have already initiated innovation hubs, drawing together AHSCs and AHSNs, which reach to a wider community. Other bidders that do not currently have an AHSC should be encouraged to explore alternative organisational groupings, for instance building arounds BRCs. There will need to be an updated taxonomy for the designation of centres of innovation to avoid multiple, disjointed layers.

- **Compete then collaborate** – the initial onus should be on strong competition for the finite resources available. Once allocated, the onus should then shift to collaboration between innovation hubs/clusters, particularly around specific diseases and data convergence. Accreditation should last for five years, as with AHSCs and BRCs, and could dovetail with the forthcoming AHSC process in 2018, subject to the point above about encouraging other competitors.

- **Focus on the value proposition** – bids should have been developed between the NHS, universities and industry at the outset. They should have a plan to attract a growing proportion of their funding from industry investment over the five year period on the basis that they will lead to economic growth for all partners, which should be a key metric for success. That is already happening in some of our leading centres, such as Oxford where Novo Nordisk is investing £115m in diabetes drug discovery.[9] The NHS has much more scope to professionalise its interface with industry so that this kind of NHS-university-industry partnership based on shared ambitions becomes the norm rather than the exception. The NIHR Office for Clinical Research Infrastructure and the Translational Research Partnerships are doing good work in this area.

- **Knowledge transfer and commercialisation** – the NHS can improve substantially its capture, protection and commercialisation of Intellectual Property, which has traditionally been seen mainly as a university role. Whilst we should not be prescriptive about how it is organised, innovation hubs should have embedded capability for effective knowledge transfer and commercialisation, so that NHS and university partners are clear on how this will be taken forward. There are now some promising tech transfer companies on which to build that have spun out of our leading NHS-university partnerships.

- **Proportionate assurance** – one of the weaknesses of national bidding processes is that the associated conditions and assurance processes can become too onerous. This stifles innovation, rather than encouraging it. Innovation cannot happen without a reasonable tolerance of risk. This requires a significant cultural shift from how most NHS activity is funded and regulated. The NIHR competition processes for BRCs, CRFs and MICs have had an appropriate degree of rigour without mandating micro-detail about how funding should be spent and a similar approach would give organisations autonomy and flexibility to innovate.

Data integration

22. Given the high profile failures of recent years (e.g. National Programme for IT, care.data), we are sceptical about a single, national approach to IT systems and data sharing. But the NHS should make much more progress in harnessing the potential of large datasets for clinical research and population health science. This should be one of our main competitive advantages and attractions for the life sciences industry as a national health system. Indeed, we are starting to realise some of that potential, but in more localised systems, for instance with the investment by DeepMind in integrated and mobile clinical systems in London,[10] or the GSK sponsored Salford Lung Study which used e-health records for a novel type of RCT across Greater Manchester.[11]

23. We strongly support the proposal in the Life Sciences Strategy for Digital Innovation Hubs that can provide sufficient scale and dynamism to make a reality of large, convergent datasets. Whilst having autonomy, their digital strategies should be in line with the recommendation of the Wachter Report to 'ensure interoperability as a core characteristic of the NHS digital ecosystem to support clinical care and to promote innovation and research'.[12] That will be an important enabler of research collaborations across regions and innovation hubs.

24. One of the most successful examples we are aware of in the NHS of how large datasets have been pooled, made convergent and used for research is the Health Informatics Collaborative (HIC).[13] This is a collaboration between Oxford, Cambridge, Guy's and St Thomas', Imperial and University College London Hospitals, sponsored by the NIHR. Over the last four years, it has created meta-datasets within an inter-institutional 'safe haven'. Critical factors for success have been CEO and board level commitment to the project across the five trusts, deep engagement of the university and NHS IT communities, and the attention paid to data cleansing and convergence.

25. The HIC project has cost c.£8m, so it has been possible to make significant progress in this area with modest investment. Whilst we do not believe there should be a single solution imposed everywhere, we would recommend HIC as a model of data convergence for others to consider, adapted to circumstances elsewhere as appropriate.

Investing in science, research and innovation and upgrading infrastructure

26. The UK spends less on life sciences research than other leading countries. However, it outperforms competitors for return on investment. The Industrial Strategy commits to increasing investment in UK R&D by an additional £4.7 billion by 2020/21.[14] This is very welcome, of course, and we hope that a significant proportion will be committed to life sciences, given the strong ROI generated by the sector.

27. BRCs have been able to leverage industry investment and grant funding of between £5-10 for every £1 of taxpayer funding.[15] MICs have done similar, so the precedent is set for NHS and university partnerships to work cohesively with the life sciences industry to generate growth. The

process of bidding for innovation hubs/clusters should aspire to use Government funding as a catalyst over five years with a view to building in longer term sustainability. Public funding could support proof of concept, prior to attracting commercial investment, for example through a reinvigorated Small Business Research Initiative.

28. To improve their 'pull through' capability, research active NHS hospitals might be encouraged to put in place innovation teams of staff who are wholly focussed on accelerating clinical trials and testing innovations. This would both avoid the time lag in recruiting separate teams for specific projects, and avoid staff being diverted by the competing burden of a clinical service role. Once proven, this could attract industry as an accelerated pathway from clinical trial to adoption and commercialisation, but it would require upfront investment to put the capability in place and to provide the initial staff 'headroom'.

29. At present, the lack of headroom in the health service is a major potential risk to the NHS being able to step up to an economic growth role in the life sciences sector deal. In this decade, we are spending a diminishing proportion of GDP on health and the NHS is under severe financial pressure.[16] This could limit the space and ambition for its workforce and organisations to innovate.

30. There are practical examples of how the funding squeeze affects the ability of the NHS to focus on research. NHS commissioners are often unwilling to fund the excess treatment costs associated with research active hospitals that have numerous clinical trials.[17] Separately, there have been recent proposals from NICE and NHS England to stage the roll out of medicines of proven efficacy that are predicted to cost the NHS more than £20m p.a. in aggregate.[18] We have given reluctant and cautious support to that proposal as a pragmatic way to manage down extra cost pressures in the short term.[19] However, we also note the negative impact this is likely to have in the longer term, both on patient access to new medicines and as a partner to pharma. Whilst regrettably necessary in the short term, it is a counter-strategic measure and we should instead be throwing our weight nationally behind the direction of travel set out in the Accelerated Access Review, which envisages a central role for major centres with AHSCs and BRCs.[20]

31. If we want a high quality health service that is an investable proposition for industry, then the country will have to find a way in the future of returning NHS spending to somewhere closer to the long term trend.[21] The life sciences sector deal is an opportunity for the NHS to be repositioned as an engine of growth, not just a consumer of expenditure. For the present, the NHS brand remains strong, access standards are impressive compared to other countries, the workforce is highly skilled and international surveys show we are a relatively lean and high quality system.[22] Our health service therefore provides an excellent platform for wider economic growth if we can realise the synergies with academia and industry. The context of Brexit and the Industrial Strategy represents a unique point in time to deliver this change.

32. In addition to revenue funding, we will also need to find ways to address the major shortage of capital investment in the NHS. The Spending Review will hold NHS capital to a flat cash allocation of £4.8bn p.a. until 2020, which will reduce in real terms with inflation and is further eroded by capital to revenue transfers to shore up current spending.[23] The need for capital investment has been underestimated across the board; for primary, hospital and research facilities, and for IT infrastructure. It is essential that clinical and research facilities are adequately maintained and updated so that we can keep pace or stay ahead of competitors in our ability to supply the latest

diagnostic and therapeutic equipment, and deliver the NHS component of the triumvirate with universities and industry.

33. We should explore innovative ways to raise capital, potentially off the highly constrained NHS balance sheet. This could not only have the effect of opening up the amount of capital available to generate sector growth, but attracting venture capital from the City or from the US could also go hand in hand with a greater tolerance of risk that is necessary to support a more innovative and entrepreneurial culture. The ROI that the sector generates could attract such investment.

34. In addition, there are significant opportunities to raise public capital for reinvestment within the NHS by selling prime estate in cities where buildings are no longer fit for purpose and the land is exceptionally valuable.[24] This requires bold, strategic planning, but could generate substantial benefits for the NHS and life sciences. It makes sense financially and could improve adjacencies by re-locating clinical, teaching and research facilities to a single campus that can support the whole innovation pathway. There are good examples of where cities are developing integrated campuses already, such as in Manchester, Birmingham and Cambridge, among others, but we should also learn from global exemplar innovation eco-systems in the US, Northern Europe and East Asia.

Supportive regulation

35. There are significant gains to be had from streamlining the regulation of basic science, clinical trials, lower risk research, and the overall regulation of NHS organisations, to encourage a greater focus on innovation while preserving high standards of clinical and research governance.

36. Brexit presents opportunities for deregulation, which should be considered in the context of requirements for our main export markets. It should be possible to revisit the requirements of the European Clinical Trials Directive and other legislation.[25] The regulatory approvals required, even for low risk, or non-invasive diagnostics, can often seem wholly disproportionate to the level of risk. We are currently at a disadvantage because it is easier to undertake animal research in other countries, and pharma can more easily recruit patients to trials elsewhere. Conversely, we can build on our relative advantage over other countries in stem cell research.

37. The Health Research Authority is heading in the right direction in attempting to streamline regulation, although there is a long way still to go. Brexit may now be the catalyst for renewed impetus to that agenda. The UK could develop a bespoke regulatory process that speeds up the time it takes to get a medicine from trial to licence as a flagship policy to attract industry within the sector deal. Any modifications to regulation, however, should be assessed for their potential impact on export requirements.

38. Looking beyond research specifically, there is a major structural issue with the many ways in which the NHS is regulated if we want a more innovative health system. The total burden of regulation from NHS England, NHS Improvement, the Care Quality Commission, and others, stifles and preoccupies NHS organisations. As the funding situation has become more difficult, the regulatory response has been to pull the reins ever tighter from the centre.[26] It is difficult for NHS boards to devote significant time to research, or innovation in the broader sense, and they are little incentivised to do so when they are being judged overwhelmingly on short term financial control and narrow waiting time targets. Redressing this would help NHS organisations to reach their potential as life and health sciences engines for economic growth.

39. There must be far greater recognition by NHS regulators and commissioners of the wider role played in the economy by our major research centres. Whilst we do not ask that NHS regulators broaden their remit, we do think the assessment of university hospitals should reflect a more balanced understanding of the value created by leading edge research and innovation. For example, the board of an NHS university hospital should not only be judged by their financial bottom line and percentage of people seen in A&E within four hours, but on the number of clinical trials undertaken, patents filed, and value created through IP. As well as adopting a narrow definition of success, NHS regulation is also intensely risk averse, and this is the enemy of innovation. These are fundamental cultural shifts from how the NHS is regulated now, but we must start to tackle these issues if we want top NHS organisations to have the space and incentives to lead the way on innovation.

Developing skills

40. Across the Shelford organisations, we employ over 100,000 people and we are some of the largest employers in our cities and regions. We are well positioned to connect the new approach to training and education set out in the Industrial Strategy and Life Sciences report with major employers across the country, for instance through partnerships with Institutes of Technology.

41. We agree on the importance of training domestically more STEM graduates, and healthcare and scientific professionals in particular, and that needs far better strategic planning than we have had up to now. The year-on-year cuts to education and training budgets in the NHS have been counter-strategic and are, in part, responsible for the shortages of clinical and scientific staff across the country. In addition, we support and would participate in initiatives in schools and undergraduate curricula aimed at raising awareness of STEM careers, at improving computational and data literacy and, in particular, redressing the gender imbalance.

42. We need a more effective and strategic approach to education which invests in training places that combine clinical practice with research and/or computer science, and which promote entrepreneurship. This should create an expanded cadre of enterprise aware clinical researchers. We also need curricula that are fit-for-purpose in the modern world, creating a much more digitally savvy workforce and preparing clinical, technical and scientific professionals to adapt during their working lifespans. This should be an important component of innovation hubs, which could specialise in particular professional courses, within a better national framework of planning to meet demand. We would hope that improvements in this arena would increase mobility of individuals between industry, academia and the NHS.

43. The visa and immigration system is a very important issue. Between 5-15% of staff in our organisations are from the EU, as well as significant numbers of non-EU overseas staff. The proportions are highest in London and the South East, but are particularly significant in clinical and scientific professions right across the country. We value overseas staff for the long term exchange of knowledge and ideas that they bring in this globalised sector; we do not just see them as a short term expedient. Along with many others in healthcare and academia,[27] we have argued for a post-Brexit visa and immigration system that facilitates the mobility of clinicians and scientists.[28] The indications are that this is the Government's intention, and that it will be a priority to secure the right to remain of current EU citizens resident in the UK, along with UK citizens resident in Europe.[29]

Procurement

44. There needs to be significantly more focus on procurement as a key enabler for the rapid adoption and diffusion of new and innovative technologies. The later adoption and diffusion stage of the innovation cycle is particularly important as it is the point at which the benefits of innovation are realised; new and improved treatments become available for patients, efficiencies are captured by healthcare organisations and industry sees a return on its investment which funds the next cycle of R&D.

45. The traditional focus of procurement across the NHS has been on unit price and cost reduction. Whilst this is important, it can be narrowly focused. We also need to work constructively with industry on rapid adoption of innovations that can have a hugely positive impact beyond the c.£6bn direct expenditure on medical technology, devices and consumables.

46. Procurement teams across the major teaching hospitals, research centres and AHSNs should develop adoption and diffusion programmes in conjunction with clinical teams. This would help to overcome the 'last hurdle' of adoption and diffusion which is often the most difficult and frustrating for medical technology suppliers; one that occurs after their investment in R&D, product trials and product development, but before the return on that investment. There are examples of suppliers switching their focus to export markets at this stage of the cycle and, whilst this may be positive for exports, the benefits to NHS patients and organisations are not realised.

47. Developing technology adoption and diffusion centres across the major NHS research organisations would also provide a more identifiable and structured 'front door' for suppliers and innovators to focus their engagement with the NHS. Their resources could be targeted more precisely, implementation timescales would be shorter and adoption and implementation evidence could be gathered more effectively to accelerate further adoption across the wider NHS.

48. A funding model for such adoption and diffusion centres should be developed, with initial seed funding and followed by a re-investment model based on a proportion of the benefits (funds/savings) from successful projects. This would provide funding stability in the initial phase to establish the processes and complete implementation of sufficient projects to move to a self-funding model.

49. Under the current financial circumstances of the NHS, trusts are often pushed to focus on in-year, cash-releasing savings, which often is not conducive to the adoption of innovative technologies or wider efficiency projects. A significantly more rounded benefit recognition and reporting process needs to be developed to encourage the development of innovation adoptions.

50. The implementation of the GS1 Barcoding Scan4Safety initiative across the system should be accelerated rapidly and some form of overarching co-ordination of resulting data should be established. The primary benefits of this programme are well known: patient safety, hospital efficiency and operational improvement, and supply chain and inventory efficiencies. However, there seems to be less recognition of the potential value of the large dataset that will be captured. The GS1 Barcoding Scan4Safety initiative will result in a large data pool of medical technology and its use across the NHS. This has the potential to be extremely valuable to the life sciences industry, innovators, clinicians and the NHS in the development of new and innovative technologies.

Conclusion

51. The life sciences sector deal will be an important part of the UK's Modern Industrial Strategy. The NHS should be a full and active partner, particularly through its major centres of research, education and innovation. We believe this can best be achieved by incentivising leading NHS organisations to work together with universities and industry as innovation hubs/clusters that will be local and national engines of economic growth.

52. This paper has outlined some of the enablers and opportunities, which we believe go with the grain of the recently published Life Sciences Strategy. In places, they will require incremental changes, but in others more fundamental cultural or systemic change. As a group representing many of the largest and most successful NHS research hospitals, we aim to play a supportive role in the development and implementation of the sector deal for life sciences.

The Shelford Group

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End notes

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