Ministerial Foreword

Dear Graham

I welcome your Commission report into how Birmingham’s potential in life and health sciences can be realised for the good of local patients and the local economy.

Bringing together industry with the assets and capabilities of our universities and the NHS is not only revolutionising the way we discover, develop and adopt innovative treatments and medicines into the health service, it boosts economic growth and helps to create high value jobs and businesses.

Your Commission and its recommendations are an important step in making this aspiration a reality and putting Birmingham in a strong position to become a 21st Century life and health science cluster.

I am particularly interested in your recommendations as to how Government should work with local partners and industry to build on Birmingham’s success in providing accelerated access to new drugs for its patient population, and to fully realise the potential of the significant investment being made in the Institute of Translational Medicine.

I look forward to working with you on the next steps.

Yours

George Freeman MP
Minister for Life Sciences
1. The Commission
1. The Commission

1.1 Introduction

We are on the brink of a therapeutic revolution which promises to transform clinical outcomes for millions of patients across the globe. There is therefore now an urgent requirement to develop new structures which accelerate the assessment of novel therapies with the aim of both maximising patient benefit and securing a sustainable business model for the biopharmaceutical sector. As outlined by the Government, this presents huge opportunities for the development of a globally competitive Life Sciences sector in the UK, and also presents huge opportunities specifically for Birmingham and the West Midlands.

At the start of this year, the Greater Birmingham and Solihull Local Enterprise Partnership (GBSLEP) Board, in its role as strategic lead for economic growth in Greater Birmingham, invited me to Chair an independent Commission to develop a ‘road map’ for growing the Life Sciences sector in the area, for economic and community benefit.

The LEP Board wished to understand how private sector investment could be maximised building on Life Sciences initiatives, including the Institute of Translational Medicine (ITM) and Life Sciences Campus, whose development the LEP has driven in conjunction with key regional partners and HM Government. In particular, the LEP Board was interested in how the region’s many strengths could be aligned to grow a world class Life Sciences sector.

It is clear that a pivotally important component of the Government’s Life Sciences vision (as articulated in the ongoing Accelerated Access Review), is the opportunity for the United Kingdom to transform the speed at which the patient impact of advances in precision medicine, devices and diagnostics can be delivered in parallel with the provision of a globally competitive regulatory environment which will drive their accelerated adoption as part of a wider innovation agenda within the NHS. This renewed emphasis on translational medicine by the Office for Life Sciences and HM Treasury presents major opportunities for Greater Birmingham.
Led by business and local authorities, the LEP provides vision, strategic leadership and knowledge to drive private sector growth and job creation in Greater Birmingham, bringing together partners from across the private, public and third sectors.

The Government’s lead mechanism for local growth, LEPs have the opportunity to demonstrate to Government what can be achieved in their area to support balanced economic growth at the national level. They also have the ability to seek support from Government in achieving this potential, as well as to influence significant funding streams such as the European Structural and Investment Funds (ESIF).

GBSLEP concluded a broad-reaching City Deal with Government in 2012 comprising five key elements in which the region’s potential in Life Sciences featured significantly:

1. A Life Sciences Accelerator focused on £12 million for the development of an Institute of Translational Medicine (ITM) to capitalise on Birmingham’s leading position in life sciences and its unique assets as a location for clinical trials;

2. A Skills for Growth Accelerator to engage employers, colleges and schools in building a best-in-class skills service linking pupils and learners with real-world work opportunities and to increase the number of apprenticeships in high growth and key employment sectors;

3. The creation of GBS Finance – a £1.5 billion fund to enable the LEP to manage, recycle and leverage public and private sector funding streams to deliver on its priorities;

4. The creation of a rolling asset-based development vehicle to unlock the potential of underused public land for housing and employment (Public Sector Assets Accelerator);

5. An expansion of the city’s pioneering Birmingham Energy Savers programme which aims to provide energy efficient improvements to 15,000 houses and 40 buildings (Green Deal Accelerator).

Since then the LEP has negotiated a £379 million Growth Deal with Government to support the creation of up to 29,000 jobs, delivery of 7,000 homes and the up-skilling of 12,500 people. This includes support for a £17 million Life Sciences campus adjacent to the University of Birmingham and the Queen Elizabeth Hospital (QEHB), and for a Future Skills Capital programme including Life Sciences.

Consequently the LEP’s prioritisation of the Life Sciences as a key engine for regional growth, coupled with its ability to act as a catalyst for partnership working, including central Government, presents a once in a lifetime opportunity to develop a world class Life Sciences sector in Greater Birmingham. It must be seized.

1.2 Commission Objectives
The objectives of the Commission have been four-fold:

1. To identify those areas of particular strength and potential to attract and grow the Life Sciences sector in Greater Birmingham – recognising that the region, whilst “world-changing”, won’t be “world-leading” in all areas;
2. To identify what local partners (including the LEP, NHS Hospital Trusts, academia and local government), Government and the private sector and other interest groups such as charities, need to do to unlock these areas of particular strength and potential, and to accelerate and magnify the benefits of key assets including the ITM, The BioHub Birmingham, the West Midlands Genomics Centre and the planned Life Sciences Campus;

3. To develop a “road map” for local partners to move forward on, working with Government, private sector, industry, venture capital and others; and

4. To identify what should be the key areas of focus for discussions and negotiations between the LEP and Government about how to realise Greater Birmingham’s potential, particularly the key areas where a response or support from Government is required.

1.3 Why me?
I am Chairman of an investment company that has had a successful history of involvement and investment in business in many different sectors across the UK and internationally. I have personally been involved in working in and developing a number of new start-ups as well as established businesses, which have created significant numbers of jobs, driven innovation and become commercial winners.

As a businessman, I have been very impressed and encouraged by the enormous opportunities for the region, with its combination of ambitious Universities and hospitals as well as active private sector businesses, to work together to take advantage of economic and health developments.

After being diagnosed with Chronic Myeloid Leukaemia in 2001 and given only 3 years to live, I was very lucky to become one of the first recipients in the world of the original ‘golden bullet’ drug STI 571 (‘Glivec’) – the very first example of personalised medicine.

As a beneficiary of early phase medical innovation that emerged from the NHS in the very first days of stratified and personalised medicine, I am therefore very much aware of the need to accelerate the translation of basic scientific advancement into drugs, devices, diagnostics and biomarkers (D3B) for patient benefit.

My personal experiences led me to co-found the charity ‘Cure Leukaemia’ in 2004, which has helped fund a regional network of accelerated trial delivery for patients with blood cancer based at the Centre for Clinical Haematology (CCH) at the QEHB. This in turn helped provide the proof of concept for the Leukaemia and Lymphoma Research-funded Trials Acceleration Programme (TAP).
The TAP, a ground-breaking national initiative based in Birmingham, has provided a highly effective translational model which has accelerated trial delivery at the same time as leveraging over £120 million worth of drugs from Pharma companies, free to the NHS, allowing many thousands of patients to benefit. Furthermore, many of these drugs and treatment regimes have, as a result, become standard of care much more quickly.

Taken together, these developments, have led to the CCH at the Queen Elizabeth Hospital becoming a recognised international centre of excellence for the treatment of blood cancers, which has driven the creation of more than 150 new jobs and led to the region becoming an important magnet for investment in clinical studies, drugs and people by the global biopharmaceutical sector.

The accelerated trials model developed through CCH and the TAP has provided a template for the subsequent development of the ITM. This will extend the principle of trial acceleration to a range of other clinical specialities, co-ordinating and utilising many of the region’s key assets to create a globally significant resource which will drive investment, job creation and accelerated clinical studies.

It is increasingly clear to me that it is this vitally important factor of speed in delivery of precision medicine, which will make Birmingham of global significance to national and international investors. For these investors ‘Time is Money’, and for patients, as I know only too well, time is everything.

1.4 Commission Focus

Through this Commission I have sought to identify how the region’s existing reputation in clinical and basic science, its proven track record and significant investment can be fully leveraged and expanded to drive the growth of the Life Sciences sector in Greater Birmingham and the rest of the UK – for both patient and economic benefit.

Consequently, some of the discussion and subsequent recommendations are deliberately wide in their scope as they are intended to act as a catalyst to enable the LEP and partners to establish strategies. Others are more specific in order to more directly focus on areas of more immediate opportunity.

It has long been the hope, and indeed has formed the underpinning rationale for billions of pounds of Government funding over the last sixty years, that a basic understanding of the molecular and cellular biology of human disease will result in the development of new and more effective diagnostics and therapeutics which will transform our ability to treat human disease.

In the last decade, the development of clinically-active targeted biological drugs and antibodies has confirmed the transformative potential of this approach. At the same time, technological advances have led to the design of both new diagnostics with the potential to deliver molecularly personalised medicine, and a range of highly effective medical devices. These dramatic changes in the immediate potential of translational medicine to transform clinical outcome have profound implications for the funding models and health economics and new
translational models are now urgently required. These will require profound structural changes in delivery models as well as greater integration of public sector delivery vehicles and the private sector. The global health and life sciences industry is extremely dynamic and a fundamental re-evaluation of current delivery models will be required if the UK is to maintain its position at the heart of the international Life Sciences sector.

As outlined by the Government, this presents huge opportunities for the development of a globally competitive Life Sciences sector in the UK and this presents huge opportunities for Birmingham and the West Midlands.

The fact that so few cities in the world co-locate the scale and diversity of population with translational, clinical and manufacturing and education strengths, presents a unique opportunity for the region to lead the world as the “go to” destination for the rapid assessment of the burgeoning array of novel therapies which is now so critical for both small and large, national and global pharmaceutical companies as well as millions of patients.

The ITM, in particular has the potential to become the region’s focal point for Life Sciences, creating many thousands of jobs and new businesses, and spawning more advances in the sector by driving the design and rapid assessment of drugs, devices, diagnostics and biomarkers (D3B) to patients in a world of 21st century precise medicine.

However, the region’s total offer is about much more than just the ITM and the purpose of this Commission has been to determine how the Life Sciences sector can be driven forward by leveraging all of the region’s assets, leading to significantly improved outcomes for patients. In particular I am aware of the region’s digital strengths, particularly with respect to medical informatics, and its exceptional track record in education.

The Commission has had direct support from central government and the Life Sciences Minister, George Freeman MP (see Foreword), who congratulated the LEP on its Commission, fully supporting the work being done and stating that this will “put Birmingham in a strong position to become a hub for the life sciences sector.”

1.5 Building the Evidence Base

I have spoken to a wide range of stakeholders and interested parties in undertaking this Commission – from Government, the Life Sciences and Pharma industry, investors, the NHS and Genomics England, clinicians, academics, the local authority, patients and charities. A full list of those I have consulted with is included in the Appendix, and I thank them all for their contributions.
2. Contextual findings
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2.1 Sector Trends
Despite continued pricing pressures and heightened regulatory scrutiny, the Life Sciences sector globally is exhibiting resilience and reinvention as it employs new R&D and business models to cost-effectively deliver innovation, value, and improved patient outcomes (Deloitte 2014).

Key drivers of growth include an ageing population, rising incidence of chronic diseases, technological advancements and product innovation, and certain anticipated impacts from health care reform provisions, including increases in government funding and insurance coverage.

Established Life Sciences activity in the UK remains concentrated in the “golden triangle” in the South East connecting London, Cambridge and Oxford. However, there are strong and emerging clusters elsewhere, including the largest concentration of medical technologies activity in the Midlands (Office for Life Sciences, 2015).

Sector trends, which offer significant opportunities for Greater Birmingham, include:
- Growing demand for the development of new therapies which, combined with rising costs and timeframes for taking new treatments from ‘bench to bedside’, is driving an urgent need for more cost-effective, faster clinical assessment. This includes a need to recruit patients quickly to trials and to access integrated patient data (diagnostic, pathological and clinical) with the potential to generate ‘real world’ data that is suitable for registration;
- A genomic revolution, specifically the advent of whole genome sequencing, which is underpinning a new era of targeted, and ultimately, personalised medicine, increasing demand for access to genetically diverse populations for trials, particularly in rare disease areas;
- Growing industry concern for new ways of competing such as via the adoption of digital technologies, development of diverse and dynamic partnerships (including between large pharmaceutical companies and smaller firms and with academia, suppliers, customers and Governments) and by accessing new talent pools;
- A strong outlook for the UK medical technology sector, which has shown the strongest growth rates since 2009 (c6% turnover and >8% employment growth) compared to weak turnover growth for medical biotech (c4%) and particularly pharma.
2.2 Government policy

Greater Birmingham has leading potential to support the delivery of national policy objectives expressed in the Government’s 2011 ‘Strategy for UK Life Sciences’:

- To find ways to make the UK better at rewarding and recognising innovation so that they can be adopted more rapidly across the NHS, including by developing an infrastructure which connects academics, industry, investors, clinicians and the NHS;
- To develop more progressive regulatory processes that ensure public safety in a streamlined way, enabling the UK to compete with countries such as the US and Germany which have developed simplified processes; and
- To attract, develop and reward the best talent, which tends to be highly mobile.

In particular, there is significant opportunity for the region to contribute to the objectives of the current Accelerated Access Review into how to create a ‘lit runway’ for faster patient access to cost-effective and innovative medicines, devices and diagnostics, including an examination of:

1. Potential reforms to accelerate access for NHS patients to innovative medicines and medical technologies (including devices and diagnostics), making our country the best place in the world to design, develop and deploy these products.

The review is focused on three key areas of potential reform and could include the role of statutory bodies including NICE and MHRA:
1.1. regulation – how we could more quickly assess the safety and efficacy of innovations by adapting systems and better exploiting our unique advantages as an integrated healthcare system with world-renowned research medicine ethics and infrastructure;

1.2. reimbursement – how we might adapt our systems of health economic assessment to: reflect technological advances in genomics, precision medicine and informatics; take time and risk out of the traditional Research and Development model; and better exploit the potential of our integrated healthcare system to pioneer new models of reimbursement for innovative products, including payment by results and Evaluation through Commissioning; and

1.3. uptake – how the NHS can better support and drive medical innovation (including through specialist commissioning).

2. How to better align existing assets and initiatives in a faster and more navigable ‘lit runway’ along the development pathway for innovative medicines, devices and diagnostics, from proof of concept through regulation, cost-effectiveness assessment and adoption and diffusion in the NHS;

3. How to develop an ambitious framework to support and drive medical innovation, and identify opportunities to increase the impact or reduce the cost of delivering healthcare to NHS patients;

4. What the long term landscape for innovation adoption should look like – including where there are currently barriers to and opportunities for innovation and potential solutions for faster adoption, including the role of NIHR in the evaluation and assessment of innovative medical technologies in a clinical setting; how the Early Access to Medicines Scheme might be strengthened, requirements for real-time data and monitoring when innovations are applied in the NHS, and how the NHS can collaborate to provide real life evidence of utility and cost effectiveness;

5. How the NHS could both accelerate access for patients and healthcare providers to innovation whilst considering cost pressures on the system;

6. Emerging technologies, including advances in digital technology, stratified medicines and their partner diagnostics, digital devices, apps and new therapeutic technologies and whether current funding structures and ways of working best support innovation;

7. How to best accelerate the use of data and measurement to drive evidence-based development and commissioning of effective innovative medicines, devices and diagnostics;

8. How to ensure patient trust in the regulation and assessment of medicines and medical technology; and

9. How our system could generate long-term incentives for development in currently under-incentivised therapeutic areas.
3. Greater Birmingham’s key strengths, assets and opportunities
I was warned by one of the most successful Venture Capitalists and philanthropists in the UK, that nearly all regions claim to be ‘World-Class’ in Life Sciences and it must be emphasised that, whilst “world-changing”, the region is not world-leading in EVERY aspect of Life Sciences. However, as demand for new and improved treatment options gathers pace, the region is ideally positioned to drive life sciences and major improvements in healthcare options, both in economic terms as well as patient outcomes. The leadership and vision of the Universities, Hospitals and other partners in the region, having already proven invaluable, will become vital to achieving growth in this critical economic and health sector.

Greater Birmingham already has an international reputation and proven track record in clinical academic programmes, clinical trials and translational research. The region’s leading and wide-ranging capabilities in translational medicine and genomics are leveraging significant industry involvement and investment as well as generating commercial spin-out companies. The region’s key assets and strengths as a location for Life Sciences investment include:

3.1 Numerous Centres of Clinical and Academic Excellence
The region has numerous centres of clinical and academic excellence in a wide range of disease areas, including 36 in the GBSLEP area alone. This includes the largest Wellcome Clinical Research Facility in the UK, an NIHR biomedical research unit in Liver Disease, and the first CRUK Cancer Centre, the largest specialist Cancer Trials Unit in the UK and a national centre for Trauma Research. These centres of excellence are strengthened by over 17 specialist Clinical Research Networks bringing together health, academia and industry in areas including Trauma Management, Cancer Research, Paediatric Research, Stroke Research, Dementia and Neurodegenerative Diseases and Mental Health.

3.2 Unique Population Advantages
The region offers unique access globally to a large, diverse and stable population for clinical trials (5.6 million), underpinned by an integrated healthcare system, “the size of Scotland’s but with the profile of the World’s”. Importantly our population catchment offers the relatively high incidence of genetic diversity and rare diseases that is so important for the development of precision therapies and diagnostics.

3.3 Education and Skills
As the world sees a movement towards greater and advanced treatment options based on personalised medicine and the incredible strides that will be made in diagnostics from the Genomics England 100,000 genome project, Birmingham’s education and training offer will become of increasing value and importance to the region. This area of excellence is explored further below and forms an important item within the recommendations section 5.
Greater Birmingham already has a strong education provision around Life Sciences including the second largest medical school in the country and education programmes which are producing high calibre graduates in medical, biochemistry, engineering and related fields.

However, of critical importance to realising the region’s potential around translational medicine will be education programmes which effectively integrate knowledge areas and skills development (including healthcare, engineering and digital) – a major area of unmet need. According to Health Education England, this will help meet a major national unmet need via programmes being developed in the region working together with the universities and hospitals.

Some of the key areas of workforce requirement identified include trials coordinators, data managers, statisticians and pharmacists, as well as the critically important permanent pool of research nurses and bioinformaticians and analysts to support development of the region’s patient data offer including genomics data.

HE partners are already making a key and responsive contribution to addressing the skills dimension of leveraging the region’s translational offer – including action to develop an integrated education programme such as the University of Birmingham’s investment in a bioengineering programme and Aston University’s translational education activity.

The National School of Healthcare Science together with Health Education England, have also been particularly active in this area and there would appear to be excellent existing co-ordination as well as genuine opportunity for further co-operation in developing targeted educational programs around translational health.

Furthermore, Health Education England have established the Genomics Education Programme (GEP) to ensure NHS staff have the knowledge, skills and experience to enable the health service to remain a world leader in genomic and precision medicine.

### 3.4 Leading Clinical Trials Capabilities – particularly accelerated, early phase models

The region has an extensive clinical trials infrastructure (the three major trials units at the University of Birmingham represent one of Europe’s largest cluster of clinical trials centres) offering comprehensive trials expertise from ‘first-in-man’ to large, late stage studies and proven capability and a track record in design and delivery with commercial partners, strengthened by world-leading health economics expertise.

In particular, the region has leading accelerated, and PROVEN, early-phase clinical trials models (Fig 1) in cancer and specifically haemato-oncology, which provide accelerated access to large trials populations and bring together clinical expertise and specialist trials staff. These models, which have been developed at the CCH with significant philanthropic support and investment from Cure Leukaemia and the Leukaemia and Lymphoma Research (LLR) - funded TAP, are shortening trial times by 4 years on average, and have secured £120 million worth of drugs for 900 trials patients at no cost to the NHS.
The Greater Birmingham Life Sciences Commission

Fig 1:

Centre for Clinical Haematology
Developed in 2004, the CCH in Birmingham involves an integrated translational research facility co-locating patients, trials staff and clinicians combined with a regional hospitals network of research nurses and tissue bank. The Centre allows academics, clinicians and industry to work together in trial development.

It has enabled the treatment of more than 900 patients on 25 complex early and late phase trials and provided access to more than £120m worth of free drugs, many of them now approved by NICE, as well as creating 150 new jobs.

Building on the region’s 5.6m patient population, the success of the initiative has been achieved by bringing together committed clinicians in hospitals across the region and funding the trials teams of research nurses, data managers and trials co-ordinators to create an environment that allows and stimulates accelerated clinical trials. Much of this work has been funded by philanthropy from charities such as LLR, Cure Leukaemia and CRUK.

Leukaemia and Lymphoma Research (LLR) Trials Acceleration Programme (TAP)
In 2011 Birmingham was selected to lead the Leukaemia and Lymphoma Research (LLR) national Trials Acceleration Programme (TAP) on the basis of its track record in clinical trials. The TAP has developed an early phase trials network which coordinates research nurses in 13 major UK leukaemia centres through a regulatory hub of trials coordinators, statisticians and data managers in Birmingham which minimises the ‘red tape’ to establish trials, enabling the delivery of accelerated results.

The TAP programme has already recruited more than 600 haematological oncology patients, from a networked catchment region of more than 20 million patients, accelerated and wider access to early phase trials with embedded genomic stratification and translational studies in the first three years.

In its first three years of operation TAP opened nine complex early phase trials that would likely not otherwise have taken place in the UK including collaborations with eight pharmaceutical companies. Together with the CCH, LLR’s five-year investment has generated a ‘staggering’ £120m drug leverage – at NO cost to the NHS – and a significant number of jobs created. The CCH and TAP together have created more than 100 jobs.

Early results from Novartis Pharmaceuticals UK Ltd showed a 50% reduction in set-up time and significant reduction in costs per patient. In 2014 TAP’s success was recognised by an international panel, leading to an award of £0.5m over 5 years.
3.5 The Institute of Translational Medicine

At the very forefront and a beacon of Greater Birmingham’s strengths in translational medicine is the Institute of Translational Medicine (ITM) being led by Birmingham Health Partners.

Opening later this month, the ITM will significantly increase the region’s capability for translation and commercialisation of clinical and academic research, and attractiveness to industry investment.

This will be achieved by co-locating clinicians, academics, trials teams, stratified medicine patient groups and industry partners, in order to maximise their interaction, create synergies and develop productive collaborative networks, including offering industry an effective and accelerated entry into healthcare research and routes to market.

The ITM will also significantly extend the early phase trials model described in Fig.1 to other diseases, including solid tumours and rare, auto-immune and chronic diseases.

The drug leverage from the sum of these trials has the potential to significantly increase the amount of drugs and devices coming into hospitals for patient benefit, at no cost to the NHS and will dramatically swell the vital but costly Cancer Drugs Fund.

In addition, the ITM will act as a catalyst and centre of significant job creation as well as a focus for SME growth, which will be a vital cog in the wheel of driving economic growth in the life sciences arena.
3.6 Integrated Patient Data Systems and Informatics Capabilities

The potential to leverage the region’s population advantages is being enhanced via the development of integrated patient data systems between the region’s hospitals, drawing on the QEH's world class track record in the design, delivery and commercialisation of clinical decision support systems.

Most notably an initiative is underway to extend University Hospitals Birmingham’s Prescribing Information and Communications (PICS) system to Birmingham Children’s Hospital to provide integrated child and adult patient data. Furthermore, an expression of interest has been submitted to NHS England by University Hospitals Birmingham on behalf of a number of NHS, academic, public and private partners, to develop a ‘test bed’ integrated data system to support healthcare delivery and to enhance the region’s existing strengths in translational medicine.

In addition, the West Midlands Academic Health Science Network (WM AHSN) is developing a proposal for an entire UK Regional population based approach to an EIT Health “Living Lab”. This will link the region’s existing trialling, testing, modelling, evaluation and research centres to provide a diverse regional population based offer to support industrial, clinical and academic members of the Healthy Ageing Knowledge Innovation Community (KIC) (EIT Health).

The ITM will present a significant opportunity to link genomic information and consequent identification of best treatment responses to help create optimum and faster trial investigation into new personalised medicines. As there is significant commonality between the ITM and the Genomics target patient groups in areas like cancers and rare diseases, it seems sensible and a massive opportunity to add to the IT budget and ‘square the circle’ by including all patients in the same hospitals who would be candidates for clinical trials.

3.7 Personalised Medicine and Genomics Capabilities

The region has leading expertise in rare diseases and stratified or personalised medicine including the Centre for Rare Diseases and Personalised Medicine at the University of Birmingham and a central role in Cancer Research UK’s Stratified Medicine Programme.

The region also possesses a high quality genomics infrastructure and capability (centred at the West Midlands Regional Genetics Laboratory based at Birmingham Women’s Hospital and the Experimental Cancer Medicine Centre Birmingham) including the capacity to link to first class research facilities for genotyping and deep immunotherapy (mass cytometry and metabolomics).
The region’s genomics capabilities are being enhanced by the development of the West Midlands Genomics Medicine Centre (WMGMC) which will accelerate the application of genomic technologies as a core component of joined-up specialist hospital services across the region, including workforce development and significant data accumulation via a £1.4m software investment (GENIE).

Because of the region’s population assets, including its high incidence of cancers and rare diseases, the West Midlands has been targeted with achieving 15% of the total 100,000 genome sequences. This is the most in the country.

With the ITM also focusing on cancers and rare diseases, there is the potential to drive the region’s excellence in translational medicine in this area, faster and to the highest level.

### 3.8 Medical Technologies and Devices

It is vital when considering the elements that should make up a regional Life Sciences agenda, to retain a focus across the whole of the sector. The West Midlands’ rich heritage lies in engineering and manufacturing and indeed, the region is home to the largest number of medical technologies of any region – 525 – supporting 9,532 jobs and generating annual turnover of £1.2 billion. It can be estimated that around three quarters of medical technology companies in the region are undertaking R&D or manufacturing.

These companies form a key part of the Life Sciences landscape, creating employment and wealth for the region and should form part of any future roadmaps that seek to build on the region’s strengths.

### 3.9 Digital Healthcare

The region has expertise and a growing company base in digital healthcare technologies and e-health. The Institute of Digital Healthcare at Warwick University is playing a leading role, and partner initiatives such as Creative Digital Health Solutions are supporting SMEs across the region to understand and respond to real challenges in healthcare with digital products and services. Supportive clusters are also in place and being further developed for the digital and tech sectors – particularly the Innovation Birmingham campus, including the new iCentrum development, which the LEP is supporting via the Enterprise Zone.

### 3.10 High Quality Inward Investment Offer

Recent research for the LEP (OCO 2015) has benchmarked Birmingham against nine other UK cities (Liverpool, Manchester, Belfast, Nottingham, Newcastle, Leeds, Glasgow, Edinburgh and Cardiff) as a location for Life Sciences Foreign Direct Investment (FDI). This benchmarking exercise has found that Birmingham has an excellent offer in terms of industry clusters, living environment, labour availability and infrastructure and accessibility.
Interviews with a small number of Life Science FDI investors in Greater Birmingham have identified that the region’s proximity and accessibility to target markets and suppliers, centres of clinical and academic excellence and competitive operating costs (premises, labour, utilities etc.) were key attractors.

3.11 Strong and Committed Healthcare Partnerships

The region has particularly strong healthcare and life sciences partnerships which are promoting translational activity to improve healthcare outcomes including Birmingham Health Partners (BHP), West Midlands Academic Health Science Network (WM AHSN), Medilink West Midlands and Birmingham Science City.

I have been genuinely impressed with the depth and range of skills, expertise and ideas as well as the way in which all of the strategic partners in the region are truly committed to achieving the potential for change and consequently improved, new 21st century thinking towards novel approaches to patient outcomes.

All of the Universities in the region as well all of the many hospitals I have spoken to are totally behind the goal of placing our region at the heart of a global drive to accelerate new translational approaches to healthcare delivery and to grow the regional economy as a consequence.

This has been especially demonstrated by the formation of Birmingham Health Partners (BHP) as well as discussions between Universities with skills and expertise in common in areas such as Medical Devices.

3.12 Proximity to the South East

Greater Birmingham’s proximity to centres of excellence in the South East – which will be brought significantly “closer” by HS2 – offers great potential for the region to develop strong partnerships with other centres, such as Oxford, for mutual benefit whereby our strengths combine to attract global investment.

In particular, there is an opportunity to look at how our leading translational capabilities (particularly our accelerated trials models) could form an offer to other centres for translating their discoveries and to develop a more globally competitive combined inward investment offer.

3.13 Precision Medicine Catapult

If successful, Birmingham’s bid to host the Precision Medicine Catapult would enable it to draw upon the region’s patient population advantages and integrated patient data systems, strengths in informatics and clinical trials to become the national centre sought by Innovate UK, linking clinicians with diagnostics businesses to accelerate the uptake of new diagnostic tests into clinical practice.
4. Areas of urgent focus and action – potential for improvement
4. Areas of urgent focus and action – potential for improvement

In the course of meetings around the Commission I have identified some key areas of focus that require urgent attention and action if the region’s potential to grow the Life Sciences sector nationally and globally is to be realised.

Consequently, this section forms the basis for the recommendations that follow in Section 5 and should be considered together.

4.1 Public Sector Incentivisation
The current lack of incentivisation for delivery of many key aspects of the Government’s Life Sciences agenda was widely cited in my discussions with clinicians, senior administrators as well as members of the Government’s Life Sciences team.

The current inadequate financial rewards for key partners, who represent such key assets in the UK’s translational armamentarium, can result in deprioritisation with respect to other Government targets and a consequent failure of provision of adequate resources internally.

Similarly, the importance of rewarding effective collaborative interactions between busy, often cash limited public sector organisations will need to be creatively addressed if we are to develop the effective translational partnerships, which will be essential for delivery on an internationally competitive scale both within Birmingham and the West Midlands.

4.2 Intellectual Property Sharing and Value Optimisation
Currently, according to significant contributors in both the private and public sectors, until an agreement is in place that identifies an agreed and accepted method of sharing the assets of IP, the progress of trialling, proving and bringing to market new D3B (drugs, devices, diagnostics and biomarkers) outputs will be significantly slowed.

Whilst some barriers to optimally driving the area and outputs of IP are already being overcome with institutions such as UHB developing ‘risk sharing agreements’ with the private sector, it remains the case that further work is required to sort out this vitally important issue.

This includes formulating an approach to IP that recognises the need of a company to access data post-ITT that goes beyond the study reports made available to the general public. Such an approach would help make joint-working arrangements between the private and public sectors simpler, quicker and more likely to deliver better treatment outcomes more easily.
The lack of a clear approach to IP release is not only slowing outputs but also affects other very important elements critical to the process of driving through the new wave of 21st century medicine. This includes key areas such as access to finance and the use of big data in the process, both of which are vital elements in the development and improvement of treatment options.

4.3 Finance

4.3.1 Private sector investment in life science innovation

Recent commentary\(^1\) has highlighted that a lack of financial support for the UK’s Life Sciences sector – particularly in providing sufficient levels of risk capital when compared to the New York Stock Exchange, but also even sufficient operational funding – is limiting the development of the UK pharmaceutical sector.

Furthermore, as was highlighted by a recent article in the Sunday Telegraph (May 31st 2015) “Graduation time for the university spin-outs making UK science pay” there are many good ideas coming out of universities that go to waste because they do not have access to adequate funding.

Birmingham is now leading in the innovation and development of novel and essential, translational delivery mechanisms and we need to be creative in establishing private sector funding streams in order to keep ahead of the game and continue leading in this area.

The provision of Finance, or more accurately, the lack of it, is a critical element not only in holding back the development of models for early phase patient trials by providing the necessary infrastructure to run the new wave of accelerated trials, but also to enable a cohesive link with other key elements in the process such as advances in Genomic understanding of disease behaviour.

4.3.2 Finance – investment in clinical study infrastructure

One of the major Life Science assets of Greater Birmingham and the West Midlands is its ability to rapidly recruit to clinical trials patients from one of the largest and most ethnically diverse catchment regions in Western Europe and use this asset to enable rapid assessment of novel diagnostics, medical devices and drug therapies.

In order to effectively deliver genomically stratified clinical trials from such a substantial population, experience teaches that not only is a central hub capable of rapid delivery and oversight of the complex attendant regulatory issues required but also up-front investment in research nurses within partner hospitals across the region.

Where both of these key resources are properly funded, examples such as the TAP and the similarly structured US BMT Clinical Trials Network, trial delivery is optimised. Absence of funding of either the Hub or the equally critical Spokes substantially blunts delivery.

\(^1\) Financial Times, ‘City Accused of Failing to Dock Life Sciences Sector’, 30th March 2015
4.4 Data
The ability to co-ordinate patient data into a central system and to link patient records to trial targets is something that has been spoken of by government, industry and clinicians for many years now. The Office for Life Sciences have stated as a priority the desire to have “the ability to best use patient data to deliver an integrated approach across the spectrum of GP’s, Hospitals and the Care sector to form a Test Bed for innovative medicines and medtech at scale in a health population.”

Novartis in their submission to this report stated “Birmingham should aim to link their diagnostic and pathology records with clinical data as part of any future proposal and provide evidence of how real world data suitable for registration can be generated.”

SV Life Sciences, the leading international life sciences venture capital firm commented that this approach should be given precedence in order to leverage the IT and data connectivity which, together with rare diseases, the Government view as an extremely important policy priority.

In December it was announced that Birmingham and the West Midlands would provide one of the largest Genomic Medicine Centres in the country, tasked with generating 15% of the total target of 100,000 genome sequences. One of the core tools in this process will be the investment of £1.4m in a software system (GENIE) that will allow the creation of a bridging tool to bring all hospital patient records into one central repository for genomic medicine patients in the first instance, with the capability to be expanded to further cohorts of patients as required.

4.5 SME Opportunities and Barriers
Medical technology companies, of which the majority are SMEs, are the largest sector of Life Sciences companies in the region (89%). The Commission has highlighted the growing market opportunities that exist in the medical devices and diagnostics sector. In particular there are opportunities around diagnostic testing as an essential part of the health care industry (75% of clinical decisions in the UK based on a diagnostic test) and with demand for access to quicker, more accurate diagnosis rising at a rate of 10% per annum (Deloitte, 2014).

However the Commission has also highlighted that medical technology SMEs face significant market barriers associated with requirements around device evaluation, NHS adoption and procurement processes and export. Successful proof of concept work, device evaluation and even partnership working between the NHS and industry are no guarantees of future adoption and procurement success and any adoption at scale is virtually unheard of.

Medilink West Midlands, which is involved in continual and day to day engagement with SME industry within the Life Sciences sector across the West Midlands region and beyond has highlighted an SME support requirement including:
• Market access initiatives with regards to translational activity, device evaluation, clinical trials, improved NHS adoption and procurement processes, partnership working through to procurement, international sales support, supporting diversification from other industries;
• Simple, business-needs driven access to finance provision able to respond to a plethora of business requirements including both seed funding and finance for longer-term (market relevant) investments, as well as improved visibility of routes which should be delivered through trusted partners; and

• Sector-related upskilling provision including development of sector-appropriate learning pathways, clinical/industry shared initiatives, grassroots careers engagement and promotional activities and industry ambassador initiatives.
4.6 Investment Marketing and Investor Support Offer

There is an opportunity to use the findings of this Commission to strengthen the region’s inward investment marketing proposition to Life Science investors.

In particular, there is an opportunity to attract pharma and life sciences companies by strong messages highlighting the unique opportunity to undertake accelerated studies in Greater Birmingham based on the infrastructure for accelerated trials developed and the unique access the region offers to a large, diverse, stable patient population, and accompanying genomics and stratified medicine capabilities.

Other areas of strength in the investment offer, recommended by recent research (OCO, 2015), should also be highlighted. They include Greater Birmingham’s proximity and accessibility to target markets and suppliers, centres of clinical and academic excellence and competitive operating costs (premises, labour, utilities etc.), as well as its existing industry clusters and supply chain capacity (particularly around medtech), quality of life and labour force capability.

Clearly it is critical that there is consistent messaging by all inward investment partners and agencies.
5. Report recommendations – leveraging the potential
5. Report recommendations – leveraging the potential

Following discussions with many people in industry, government and academia, it is very clear that not only does the region’s Life Sciences sector have the potential to produce a growth in economic activity creating real revenues for the UK and Greater Birmingham in particular, but that it will also contribute to a more efficient NHS, by delivering more innovative technologies thereby reducing costs but most importantly, improving treatment options across the spectrum of health.

The combination of new science, the genomic revolution, improved data, innovative IP sharing and incentivisation can and will generate a better and more sustainable health economy. It should be the intention that this region begins to play a major role as a global leader in the arena of translational activity, especially via accelerated access, thereby acting as a magnet to industry for whom faster, successful trials and evaluation equates to increased revenues and profit and a stronger economy for Greater Birmingham.

A number of my recommendations are deliberately wide in their scope as they are intended to act as a catalyst to enable the LEP and partners to establish effective and appropriate strategies in the subject areas identified while others are more specific in order to more directly focus on areas of more immediate opportunity:

5.1 Partners develop an immediate joint submission to the Accelerated Access Review...

...focusing on the national-level changes required to support the development of the Life Sciences sector, and illustrating how this would make a difference in terms of accelerating patient benefits as well as unlocking sector growth in Greater Birmingham. In particular the submission should highlight:

- the potential offered and evidenced by Birmingham’s proven and leading accelerated early-phase trials models and the ITM and its population advantages and therefore its particular suitability as a location for accelerating access to innovative products for NHS patients which would be further enhanced by Birmingham becoming the location for the Precision Medicine Catapult;
- the factors that would enable the potential associated with these models to be unlocked more effectively e.g. establishment of disease-specific, early-phase trials acceleration networks and development of stronger incentivisation of Hospital Trusts and Universities and their staff to facilitate translational medicine programmes (e.g. via special project vehicle models which release IP revenues, agreed translational targets and greater rewards for major Trusts; and reforms to funding and regulatory bodies to increase their support/participation in translational research);
how the region is capable of meeting many of the Government’s aims for Accelerated Access to innovative medicines and medical technologies in one central location by virtue of its large population and existing clinical translational focus; and

the region’s particular strengths around medical technologies including a strong supply chain and service base, which, combined with the region’s population advantages, further plans to integrate patient data systems and the capacity being developed by the ITM, make this the best location to get devices and diagnostics developed quickly.

5.2 An expert panel be established amongst partners with the leadership and facilitation of the LEP...

...to develop a vision (e.g. 10 year) and strategy (e.g. 5 year) for growing a globally competitive Life Sciences sector in Greater Birmingham that will make a major contribution to the growth of Life Sciences in the UK by:

• Building on existing and proven strengths in clinical translation to become a world leading centre for accelerated clinical trials for the development and testing of novel drugs, diagnostics and medical devices, including an integrated data offer which responds to investor demand, workforce development and an attractive incentives and support framework for Life Sciences investors;

• Increasing public sector engagement and capacity for commercialisation of healthcare innovations – via the development and testing of new models of IP sharing and financing and development of an integrated education programme;

• Developing an integrated region-wide data system that links the region’s patient population and delivers integrated patient data across GP’s, Hospitals and the Care sector to form a Test Bed for accelerated access to innovative medicines and medical technologies at scale, and linked to the great strides made within Genomics in the region;

• Leveraging key areas of strength around digital healthcare, medical devices and its education offer; and

• Testing new models for translational medicine of national relevance.

The vision should include an understanding of the potential scale of the Life Sciences sector growth opportunity in Greater Birmingham and the strategy should include targets for growth (including investment leveraged, jobs created and potentially huge value of drugs secured for trials patients at no cost to the NHS) so that progress can be measured.

5.3 Discussions are commenced with Government...

...as soon as possible about how Greater Birmingham’s potential to grow the Life Sciences sector can be unlocked including as a component part of a devolution deal negotiated with the region.

There seems to be a consensus among many consultees that there are three key areas where Government support is required:

a. Public Sector Incentivisation

The current lack of incentivisation for delivery of many key aspects of the Government’s Life
The Sciences agenda was widely cited in discussions as an area that should be urgently addressed. Specifically, inadequate financial rewards for key partners, which can result in deprioritisation of translational activity with respect to other Government targets, as well as increasing the importance of rewarding effective collaborative interactions between busy, often cash limited public sector organisations, needs to be creatively addressed. This will prove vital if the UK is to develop the effective clinical translational partnerships which will be essential for delivery on an internationally competitive scale, within the Greater Birmingham region.

After extensive consultation I suggest that the Government needs to urgently explore:

- in partnership with the private sector, the creation of models which encourage and reward commercialisation by public sector Life Sciences bodies including NHS R&D structures, NHS England and Universities;
- the development of novel models encompassing both key public sector partners, private sector and finance bodies which maximise IP release from translational medicine collaborations and reward partners appropriately;
- identifying specific agreed translational targets or rewards for public sector partners including hospitals and universities and, critically mechanisms which reward their delivery; and
- incentivisation of key personnel required for effective translational delivery including leaders of R and D departments, clinical trials units and individual clinical academics and research nurses.

Specifically, consideration should be given to:

- the development of special project vehicle models, in collaboration with the private sector, to release funds generated from IP back to NHS Trusts and other partners allowing sustained funding of translational teams; and
- working within NIHR structures to increase the resource available to deliver their stated intention to “provide a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focussed on the needs of patients and the public” (2013/14 annual report).

Consequently, I recommend that the LEP should use this NIHR mission as a basis for working with the government to help focus and direct NIHR funding streams to optimise release of the clinical translational potential of networked metropolitan populations, such as Birmingham, building on the NIHR’s increased involvement in progressive regulatory processes of translational activity, and focus, and so help drive the UK’s international competitiveness.
Such focus should significantly assist the UK and the Greater Birmingham region in particular, in building on the current clinical academic reality where the new era of novel diagnostics and therapeutics presents huge opportunities for the UK to be a genuine global leader in early phase trial delivery by building a genuinely networked translational infrastructure of real scale thereby linking into and enhancing the regions offer to the private sector’s clinical translational life sciences activity.

b. Intellectual Property Sharing and Value Optimisation
It has become clear from my discussions with many key players, including large Pharma, venture capital and the public sector, that there is an urgent need to define more effective strategies allowing effective capture and equitable distribution of the substantial intellectual property (IP) which is created by translational collaborative initiatives particularly in the area of rapid assessment of diagnostics and therapeutics. The issues involved include definition of IP assets and ownership (data ownership and investment in developing products up to early phase human trials) and the subsequent need to find agreement on value and consequent profit share.

Over and above these challenges, it has been identified by many parties that IP release from the assets resident within the NHS and academia are neither identified effectively, nor released swiftly or efficiently. Given the centrally important fact that failure to identify the up-front investment in translational infrastructure such as research nurse networks and tissue banks is a major rate-limiting step in the process of release of translational assets, there is a real urgency to identify creative mechanisms by which IP can be effectively released and used to pump-prime Birmingham’s unique Life Sciences offering.

In the course of discussions, I have been struck by the creative vision around the ‘real life’ applicability of IP release consequent upon the establishment of accelerated translational structures with integrated diagnostic pathways, eloquently described by Innovate UK. It offers a potentially transformative approach to IP share, and if the UK is to fulfill its translational potential, I would encourage the LEP and indeed the government to engage with key players at Innovate UK to establish if there are ways to drive this in the region.

Innovate UK have identified the need to establish a clear approach to the sharing of IP in IIT’s, otherwise it will be increasingly difficult for large Pharma to justify investment in such trials. This requires the creation of a more open process, using special project vehicles or other such innovative models, that allows benefits to accrue to all partners. This especially requires engagement with Venture Capital and the private sector early to avoid the significant number of missed opportunities in driving innovation and so maximising IP release. There are examples of where this works well – MIT and others US institutions have an impressive track record in this area, which should be urgently examined.

I recommend that support is sought from HM Treasury and BIS for the development, testing and evaluation by Greater Birmingham partners of innovative models of IP sharing for greater incentivisation of public sector engagement and incentivisation in the translational and commercialisation of healthcare innovations.
The LEP and indeed the Government should engage with key players at Innovate UK to establish if there are ways for Innovate UK’s creative thinking around the ‘real life’ applicability of IP release to be driven forward in the region.

c. Finance

One of the main questions posed in the Government’s current Accelerated Access Review is how it is possible to create affordable, national funding models to drive innovation. It also asks how the UK can integrate and speed up national reimbursement processes and fund clinically, cost effective innovation throughout the healthcare system. A fully-funded and operational ITM can provide significant solutions to this question on a national scale.

However, inadequate funding and financing of key assets in the region, from the full trials infrastructure to the development of University spin-outs is a significant barrier to the development of the sector. There is consequently an urgent need to examine how to maximise private sector engagement to create novel financial models with the capacity to pump prime and ultimately monetise translational initiatives such as sample collection, tissue banks, genomic analysis, development of devices and diagnostics and clinical trial delivery.

Greater Birmingham is now leading in the innovation and development of novel and essential translational delivery mechanisms and so needs to be creative to establish private sector funding streams in order to keep ahead of the game and continue leading in this area.

As has been discussed by many contributors, the rapid assessment of novel diagnostics, medical devices and drug therapies requires a large, ethnically diverse catchment region such as ours, and there will be rich rewards in terms of inward investment and economic growth for the regions if we can successfully exploit this opportunity. However to date, partly because it is only recently that this wave of novel therapies has been developed, there has been almost no expert financial modelling of how best to do this.

Consequently, I recommend that the LEP continues to press the Government, again including via a response to the Accelerated Access Review, to ensure funding is made available to drive the arena of translational medicine more quickly and in a properly coordinated manner.

In the Accelerated Access Review, reference is made to examining how the £1bn NIHR budget can be more effectively used to accelerate assessment of new drugs. As mentioned above, when discussing Public Sector Incentivisation, I recommend that the LEP make strong representation to the OLS and the Department of Health to identify mechanisms by which new resource can be leveraged to supplement NIHR in order to optimize the delivery of accelerated translational research outputs from recently funded translational facilities in Birmingham.

One specific example lies in the requirement for new investment in order to make maximal use of the strategic opportunities presented by Birmingham’s huge population base. Thanks to major investment by key partners the ITM now has the capacity to act as a highly effective hub. However, unless attention is paid to developing models which fund its regional spokes there is a real risk of failure to accelerate the delivery of clinical trials.
It is worth re-emphasising that, on the basis of previous models of accelerated trials in Haematology, the leveraging potential to drive throughput of new drugs into the NHS is enormous. The prediction for the next 2 years in blood cancer trials is for a further £120m of new drugs, at NO DIRECT COST to the NHS, to be leveraged. While it is very difficult to put an exact figure on the drug leverage value from trials that will be led and delivered by the ITM, I would consider that, conservatively, there is the realistic potential to deliver at least £100m pa of free drugs directly to patient benefit. This figure would then be adding nearly 30% more drugs to the government’s Cancer Drugs Fund over the coming years.

One of the main opportunities identified during my consultations has been the potential to develop new funding models for the support of translational research. Closely linked to considerations concerning optimal IP release (see Section 4.2). Not only do these potentially have major relevance for the growth of Greater Birmingham Life Sciences but they also have broader national relevance given the emerging recognition that this issue now represents a major roadblock in the effective release of the UK’s translational potential.

From discussions with a number of consultees, five areas are worthy of suggestion for more scrutiny:

1. Firstly, the consideration of further incentives for venture capital and Industry to engage specifically and even more actively in translational medicine so that it is undertaken in an accelerated manner and able to achieve a return based on a proper IPR structure as discussed above.

2. Secondly, using the successful and proven, philanthropic engagement already existing in the region, with charities such as LLR, CRUK and Cure Leukaemia, there should be increased incentives in terms of matched funding, increased levels of gift aid or other methods of incentivisation to stimulate the many other highly effective charities, in a number of other disease areas, to embrace the move into clinical translational activity.

This is now clearly a story which has increasing traction for philanthropic bodies who will find the opportunity to work with NIHR a huge plus not only in terms of quality assurance but also prestige. Much more should be done to drive such funding opportunities and the narrative of how individual charities can help deliver the government’s Life Sciences vision can be a compelling one.

Having had discussions with the Association of Medical Research Charities and with MP’s, I am aware that there are many such organisations who would be able and keen to assist in the funding of accelerated trials, especially where the areas of disease expertise offered by the ITM match their own area of specialization. In essence, the government needs to assist charities become an integral part of accelerating the clinical translation process.

The LEP should also work with HM Treasury and DfIS to develop novel models of
private sector funding for the delivery of translational outputs. These should more rapidly enable the required up-front investment in clinical trial infrastructure and areas such as tissue banking and genomics, which is a pre-requisite to the region fully releasing the economic benefits of its uniquely strong Life Sciences assets.

These could include the potential to issue structured Bonds to fund translational research as modelled by both the Australian government and the California Institute for Regenerative Medicine (CIRM) both of which have been transformative in boosting funding for research which is solely targeted at speeding up treatments and therapies that come from medical research and getting them into the clinic more quickly.

In the course of discussions with specialists in structured finance, the legal and other professions within the UK and Greater Birmingham specifically, I have established that there is a real appetite to investigate methods of creating appropriate funds, either via Bond issues or other innovative funding models, that will create significant capital to enable these translational outputs to occur and specifically assist in driving the areas of life science excellence in both the public and private sectors, especially in Greater Birmingham.

The result of creating a sound funding platform will be to create the ability to leverage profit and capital many times over which will act as a real driver and stimulant to help capture as yet unrecognized IP value and help build a sustainable life sciences economy in the region and the UK. In addition, there is a very good chance that the public may well support such issues on the grounds that it would not only help drive the world of new patient outcomes but could also potentially offer higher rates of interest than currently available in a bank. In addition, the potential for the fund to be underwritten by government (so adding security) should also be explored.

3. Critically this innovative funding model also potentially allows a proportion of the IP, and thus profit generated, to be returned to partners thereby incentivizing delivery of translational outputs and contribute to the sustainability of this work. It is widely recognized that current incentivisation models are inadequate and the LEP should prioritize delivery of novel models with potential national relevance.

4. The increase in the level of involvement in ERDF applications via a dedicated position at the ITM to maximize specifically targeted investment funding.

Through these suggestions my intention is to encourage a supportive national “policy” framework including public sector incentivisation and reward and R&D structures for the throughput of novel treatments. In addition I want to encourage innovative funding options that will support the extension of the region’s accelerated trials model (on the back of the ITM as the hub and including the development of ‘spokes’ across the region’s hospitals) to create a natural cluster and environment for world-class translational activity, including an integrated data platform across the region’s main 18 hospitals.
5.4 Data
The importance of co-ordinating patient data into a single central repository in order to link patient records and help more accurately populate trials is something that has been spoken of by government, industry and clinicians for many years now. The Office for Life Sciences have stated as a priority the desire to have “the ability to best use patient data to deliver an integrated approach across the spectrum of GP’s, Hospitals and the Care sector to form a Test Bed for innovative medicines and medtech at scale in a health population.”

As such, a major element in driving investment, economic growth and a more efficient and effective NHS is the development and enhancement of the power of data and digital technology. The ability to better utilize data will stimulate efficiency not only in terms of reducing costs but also by allowing earlier diagnosis, improved care pathways and eventually the treatment of patients in a more targeted and effective manner.

The ITM will help develop a significant opportunity to link genomic information and consequent identification of best treatment responses to allow optimum trial investigation and speed into new personalised medicines. As there is significant commonality between the ITM and the Genomics target patient groups in areas like cancers and rare diseases, it seems sensible and a massive opportunity to add to the IT budget and ‘square the circle’ by including all patients in the same hospitals who would be candidates for clinical trials.
I recommend that partners continue their efforts to request funding by developing a ‘test bed’ proposal for developing an integrated data system to support healthcare delivery and to enhance the region’s existing strengths in translational medicine. Such a system should link the complementary target patient groups of both the ITM and Genomics England across the region’s 18 hospitals and the wider care sector and so combine diagnostic, pathological, genetic, clinical data, social care and social media data, thereby demonstrating capability to generate ‘real world’ data suitable for registration studies.

5.5 Education

As has been stated above Birmingham and the region are key players in the national “100,000 genomes project” which has the potential have a fundamental impact not just on healthcare but economic growth. Put very simply, inside the next 10 years many employees in life sciences in both the public and private sectors – from GP’s to nurses, technicians to radiologists – will need to have a greater understanding of genomics because of the impact on their work, for instance, of prescribing antibiotics that are specific to a person’s genome. The LEP could be a national leader in supporting the delivery of these advances and at the same time strongly augmenting Birmingham’s reputation as a knowledge centre for training, education and best practice in life sciences.

Following discussions with a number of people, I recommend that there is a concerted effort to develop the opportunity to use finance from sources such as the European Structural Investment Funds, particularly the European Social Fund to drive high quality education and training and placement activity for the life sciences growth sector. On the back of the Genomics revolution there is a real opportunity for the region to lead in training at all levels to take advantage of this major change in how the health professionals, in every aspect, approach the new sea-change that will evolve in how all patients are treated in the not too distant future. In 10 years’ time, many experts are predicting that all aspects of treatment from primary to acute care will be on the basis of genomic input.

This gives the region a fantastic opportunity to lead in this aspect of education and training by leveraging the skill base in both the public and private sectors and enhance its reputation as a leader in this emerging new world of health delivery.

I recommend that the work already being undertaken by HEI partners and the National School of Healthcare Science together with Health Education England is integrated with the excellent work being undertaken by the LEP-initiated Greater Birmingham Employment & Skills Board to develop a demand-led employment and skills provision.

Furthermore, I suggest that requirements associated with unlocking Greater Birmingham’s potential around Life Sciences form a key part of any devolution deal negotiated with Government. I note that the ‘skills deal’ proposal is due to be submitted to Government at the end of the month.
Two specific initiatives have been mentioned:

1. The provision of training and education courses around the specific area of translational delivery is an area of real potential and unique excellence. The creation of courses for the training of research nurses, data managers through to the trials coordinators, pharmacists and statisticians should be considered in order to meet the demand that will begin to grow globally as well as further reinforcing the region’s reputation within the arena of translational medicine.

2. I have received many representations that science-based training is under-funded, in particular projects that bring the public and private sectors together and which aren’t funded by Universities. These might include joint placements, vocational training, public/private courses on translational research and innovation. The cost of these could be funded through the European Social Fund and should be investigated.

At a national level, work already being undertaken by the National School of Healthcare Science and Health Education England, and located in Edgbaston, has enormous potential to be developed to continue the education and training of personnel in all areas to drive the wide ranging understanding and value of life sciences via education and training and to reinforce the region as a leader in the field.

5.6 SME Support

In the light of SME barriers and support requirements, highlighted by Medilink WM in particular, I recommend that consideration be given to how the Growth Hub being developed by the LEP can help unlock business formation and growth in response to opportunities in the Life Sciences sector.

There are already a number of important initiatives in this area that have been developed by partners in Greater Birmingham such as Creative Digital Health Solutions, Innovation Engine, and the Entrepreneurs for the Future (E4F) tech incubator at the Innovation Birmingham Campus. Furthermore, the new ‘Access to Finance’ portal developed by the LEP and DPS Birmingham and plans for a European funded region-wide SME loan and equity fund are expected to improve SMEs across sectors to access to finance.

I recommend that a further review is undertaken by partners of the financing gaps and any specific support needs of SMEs looking to enter the healthcare and life sciences markets, and how these can be addressed through the development of the Growth Hub in a way that is integrated with the sub-region’s growing Life Science asset base including the Life Sciences campus.

5.7 Private investment and life science company involvement

In a rapidly changing environment it is essential that new potential investment is attracted to the Birmingham region. Life sciences companies (national and international) should be made aware of the region’s unique potential as a location for the fast and efficient development and testing of diagnostics, medical devices and medicines. Specifically, because of the benefits to all
concerned in accelerating the study and access to innovative drugs, the ITM should develop greater relationships with Pharma in order to drive not only IIT’s, but also more commercially supported clinical trials with newly developed personalised medicines.

5.8 Partnering with other locations
It has been suggested by several parties, that by partnering with life sciences companies and laboratories in other regions (e.g. in Oxford due to its close proximity and existing working relationship with the region), Greater Birmingham could more easily and quickly identify ways of leveraging industry investment from a combined offer of strengths in basic science, research and output and Greater Birmingham’s accelerated translational capabilities (e.g. the development of a “Broxford” axis).

If the right environment is developed to enable regions to work together, it will help the UK to reap the rich dividend of treatment options and Life Science sector growth considerably more quickly. In addition, this acceleration of outputs will act as a significant magnet to draw in industry – especially SME’s – to the region.

I recommend, therefore, that a partnership be explored with other locations such as Oxford.

5.9 Inward Investment
I recommend that:
• partners should work with Marketing Birmingham and UKTI to ensure that promotion of Greater Birmingham’s inward investment offer as regards Life Sciences reflects the strengths highlighted in this report;
• work is undertaken to engage national and regional investors and funders who have a commitment to the life sciences sector and the region in particular e.g. Midven, Mercia Fund and Finance Birmingham;
• work is undertaken to identify ways of leveraging investment by identifying public sector seed corn or match funding opportunities [e.g. by attracting Medical Research Council Catalyst funding for early phase trials – demonstrating the potential to provide patients for trials quickly and with specific sub-set diagnosis]; and
• consideration be given to how wider investments could support the enhancements of the region’s already strong offer as a location for Life Sciences investment e.g. investments in transport and digital connectivity.
6. Concluding remarks
I have been extremely impressed by the desire, drive and belief within the region to grow its life sciences activity and to really focus on and exploit the core assets that exist in Greater Birmingham. By doing this, the region has the potential to significantly contribute to the growth and development of the health economy within the clinical translational sector while at the same time helping the government achieve its health priority of enabling greater and faster patient access to new treatments, drugs and devices and consequent better outcomes.

It is predicted that the next 10 years will see a sea-change in the way health professionals treat all patients, with 21st century advances in personalised medicine and Genomics radically altering current approaches. The scale and opportunity for the region to lead in development of these advances is enormous and certainly very realistic.

Having already invested heavily in developing infrastructure as well as having achieved a tangible, proven and global reputation for delivering a model of accelerated access in a relatively rare disease discipline, the potential to drive this on in more and larger patient disease groups is inarguable. The consequent economic growth that could accrue to the region is therefore significant and truly exciting on a number of fronts.

It would appear that the biggest threat to the ability of the region to establish a world class Life Sciences sector would be posed by failure to immediately identify the funds required to rapidly release the largely untapped translational potential resident within Birmingham and the region’s massive catchment region. The phrase ‘Time is Money’ has been used before in this report and this principle will, in the end, be the deciding factor as to which region, not just nationally but across the world, can steal the march on its competitors. If the region, in the short term, does not grasp the many opportunities it is surrounded by, it may well be surpassed by others and lose the distinct and real potential to develop a global reputation as a leader in translational life sciences.
7. Appendix: List of contributors
I would like to formally thank everyone from across the Healthcare, Academic, Industry and Finance spectrums from across the country who has willingly and enthusiastically given their time and opinions as to how this region can best drive its position in the Life Sciences arena. I would also like to offer my grateful thanks to Katie Judge from the LEP Executive for her support during this Commission.

George Freeman MP
Karen Booth
David Griffiths-Johnson
Dilip Chauhan
Chris Dall
Anoop Maini
Jenni Ord
Chris Gibson
Mandy Shanahan
Angela Daly
The Rt Hon Jacqui Smith
Angela Maxwell
Tim Jones
Dr Graham Lipkin
David Taylor
Matthew Doazman
Professor Ros Keeton
Tim Woodhead
Professor Matthew Cook
Harjinder Kang
Mark Hackett
Dr Tom Clutton-Brock
Professor Dion Morton
Professor Charles Craddock
Professor David Adams
Anne Simper
Gurmit Kler

Office for Life Sciences
Office for Life Sciences
Office for Life Sciences
Office for Life Sciences
Precision Medicine Catapult
Innovate UK
Health Education England
Health Education England
Health Education England
National School of Healthcare Science
University Hospitals Birmingham NHS Foundation Trust
University Hospitals Birmingham NHS Foundation Trust
University Hospitals Birmingham NHS Foundation Trust
University Hospitals Birmingham NHS Foundation Trust
University Hospitals Birmingham NHS Foundation Trust
University Hospitals Birmingham NHS Foundation Trust
Daventry Children’s Hospital
Daventry Women’s Hospital
Daventry Women’s Hospital
Heartlands Hospital
Sandwell and West Birmingham Hospitals NHS Foundation Trust
Royal Stoke Hospital
Institute of Translational Medicine
West Midlands Genomics Medicine Centre
University of Birmingham
University of Birmingham:
University of Birmingham:
University of Birmingham:
Professor Pam Kearns  University of Birmingham:
Professor Dame Julia King  Aston University
Professor Chris Hewitt  Aston University
Professor Ian Blair  Birmingham City University
Dr Christopher Parker CDE  West Midlands Academic Health Science Network
Tony Davis  West Midlands Academic Health Science Network
Richard Stone  Medilink WM
Mike Carr  GDSLEP
Paul Dransfield  Birmingham City Council
Neil Rami  Marketing Birmingham
David Hardman  Innovation Birmingham
Dr Pam Waddell  Birmingham Science City
Gaynor Fryers  ex-Astra Zeneca
Barbara McLaughlan  Novartis
Mike Standing  Deloitte
Kate Bingham  SV Life Sciences
John Moulton  Better Capital
Sue Summers  Finance Birmingham
Sam Miller  Finance Birmingham
Charles de Rohan  The Dinding Site
James Wilkie  Alta Innovations
Mark Lee  Cal thorpe Estates
Jayne Herrity  Cal thorpe Estates
Emily Crossley  Duchenne Children’s Trust
Chris Dunce  Leukaemia and Lymphoma Research
James McLaughlin  Cure Leukaemia