



Llywodraeth Cymru
Welsh Government

Genomics for Precision Medicine Strategy

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This document is also available in Welsh.

Genomics for Precision Medicine Strategy

Executive Summary

New genetic and genomic technologies have the potential to revolutionise medicine and public health. This Strategy sets out the Welsh Government's plan to create a sustainable, internationally-competitive environment for genetics and genomics to improve health and healthcare provision for the people of Wales.

In March 2016, the Welsh Government published a Statement of Intent (Sol)ⁱ outlining the key principles that would underpin the development of a Genomics for Precision Medicine Strategy. Since March, the Taskforce has consulted widely with stakeholders through a series of workshops, focus groups and 1:1 meetings, and feedback and comments from these meetings has informed the development of the Strategy. The Strategy outlines the key initial actions, as part of a 5-10 year plan that will:

- Develop internationally-recognised medical and public health genomics services in Wales – that are innovative, responsive and well-connected to the major genetics and genomics initiatives that are evolving worldwide.
- Develop internationally-recognised research in genomics and excellent platforms for precision medicine, with All-Wales leadership and coordination and strong links to clinical genetics.
- Be outward-looking, and actively seek out partnerships that can strengthen genomics and precision medicine services and research in Wales, with a focus on those partnerships that will bring the biggest benefits for patients.
- Develop the NHS and research workforce in Wales, in recognition that this investment will have the biggest impact on our ability to realise the potential of genomics and precision medicine for patient benefit.

A summary of the key actions proposed is outlined below.

Actions

Co-production – working with patients and the public in genomics

1. **The Wales Gene Park and the All Wales Medical Genetics Service All Wales Medical Genetics Service will work with the citizens of Wales to support the development of an open, transparent and publically agreed approach to the sharing of genomic and precision medicine data for service development and research [\(page 7\)](#).**

Clinical and laboratory services

2. **The Welsh Health Specialised Services Committee (WHSSC) will retain a specialist national commissioning model for All Wales Medical Genetics Service that is fully engaged with all Health Boards and NHS Trusts. It will develop a commissioning strategy that is nimble and responsive to rapidly changing demands for genetic, genomic and precision medicine services for a range of clinical specialties. Welsh Government and WHSSC will work with All Wales Medical Genetics Service to predict the future requirements for genetic, genomic**

and precision medicine services and will consider a protected development fund to enable timely adoption of new capabilities/services ([page 11](#)).

3. The Welsh Government will work with CVUHB to further develop the All Wales Medical Genetics Service as an All-Wales Service. Mechanisms will be developed to include NHS Wales Health Boards, NHS Trusts, WHSSC and other key partners in governance and oversight structures for All Wales Medical Genetics Service, to ensure that it fully reflects All-Wales service, teaching and research interests ([page 11](#)).
4. Welsh Government will convene key stakeholders, including NHS Wales, NHS Wales Informatics Service (NWIS), All Wales Medical Genetics Service, Wales Gene Park and Higher Education Institutes (HEIs) in Wales to develop a strategy for networking capability to support the transfer of genomic and precision medicine data. This will include the capability to receive and send patient and sample data within Wales, out of Wales and with academic and commercial partners. It will also seek to understand the distinctive Information Governance requirements associated with sharing and linkage of genomic data, and ensure that a clear, transparent approach is designed in co-production with the Public ([page 11](#)).
5. A business case will be in year one for short and long-term accommodation solutions for a genomics laboratory suite with sufficient capacity for future growth and ability to accommodate the requirements and genomic facilities of partner organisations ([page 11](#)).

Research and Innovation

6. The Wales Genomic Medicine Centre (Genomic Medicine Centre) will be developed as a virtual centre, built upon close working between the Wales Gene Park and All Wales Medical Genetics Service. The Genomic Medicine Centre will support Wales' involvement in the 100,000 genomes project and act as a focus for the translation of genomic research into NHS Wales ([page 14](#)).
7. As part of the 100,000 genomes project, the Wales Genomic Medicine Centre will work with the Secure Anonymised Information Linkage databank (SAIL) to identify mechanisms for linking genomic data to health and other data held within the SAIL databank ([page 15](#)).
8. All Wales Medical Genetics Service and Wales Gene Park will work together to review models of consent within All Wales Medical Genetics Service and develop a proposal for routine research access to surplus clinical genetics samples and data, laying the foundations for a unique platform for precision medicine and genomics research. This work will be developed in collaboration with patients and the public and be informed by the principles laid down in the information governance project (see 4., above) ([page 15](#)).

Workforce

9. Welsh Government will work with NHS organisations to ensure that the genomics training needs of All Wales Medical Genetics Service, the Welsh Blood Service and Public Health Wales are reflected in Integrated Medium Term Plans. This will include further Scientist Training Programmes and Higher Specialist Scientific Training (Higher Specialist Scientist Training) posts in genetic counselling, bioinformatics, genomic science, microbiology and molecular pathology and ST training posts for Clinical Geneticists, as required ([page 17](#)).

- 10. Working with Welsh Government, Health Education Wales, Local Health Boards , NHS Trusts, Clinical Leads and the Health Science Strategic Workforce Group, All Wales Medical Genetics Service will lead on a scoping and capacity modelling project to determine training needs of the wider healthcare and academic workforce in genomics. Building on the recommendations made, Welsh Government will work with Health Education Wales to ensure that appropriate training opportunities and programmes in genomics and precision medicine, such as part-time funded MSc Genomic medicine courses and continuing professional development opportunities, are available to NHS Wales staff ([page 17](#)).**

Strategic partnerships

- 11. The Welsh Government will develop the capability for strategic coordination for industry engagement in genomics for precision medicine in Wales ([page 21](#)).**
- 12. A lead organisation will be appointed to work with partners (including All Wales Medical Genetics Service, Wales Gene Park, Public Health Wales, Wales Cancer Bank, Welsh Blood Service, Life Sciences Hub, Health and Care Research Wales, NHS Wales, Health Technology Wales, HEIs and third sector organisations) to develop a business strategy and a model Framework Agreement for Industry Engagement in genomics for precision medicine ([page 21](#)).**

Abbreviations

AOMRC	Academy of Medical Royal Colleges
AWGL	All Wales Genetics Laboratory
AWMGS	All Wales Medical Genetics Service
AWTTC	All Wales Therapeutics and Toxicology Centre
CLIMB	MRC Cloud Infrastructure for Microbial Bioinformatics
CPD	Continuing Professional Development
CRUK	Cancer Research UK
CVUHB	Cardiff and Vale University Health Board
ECMC	Experimental Cancer Medicine Centres
ETTF	Efficiency Through Technology Fund
GMC	Genomic Medicine Centre
HEI	Higher Education Institution
HEW	Health Education Wales
HSST	Higher Specialist Scientist Training
HTF	Health Technology Fund
IMTP	Integrated Medium Term Plans
IP	Intellectual Property
LHB	(Welsh) Local Health Board
MDT	Multi-disciplinary team
MRC	Medical Research Council
NCMH	National Centre for Mental Health
NGS	Next Generation Sequencing
NWIS	NHS Wales Informatics Service
PHW	Public Health Wales
SAIL	Secure Anonymised Information Linkage Databank
SBRI	Small Business Research Initiative
STP	Scientist Training Programme
WCB	Wales Cancer Bank
WCRC	Wales Cancer Research Centre
WCTU	Wales Cancer Trials Unit
WGP	Wales Gene Park
WBS	Welsh Blood Service
WHSSC	Welsh Health Specialised Services Committee
WTAIL	Wales Transplant and Immunogenetics Laboratory

Genomics for Precision Medicine Strategy

Introduction

New genetic and genomic technologies are allowing us to develop a much more detailed understanding of the link between our genes and health. In recent years there has been international recognition that these technologies have the potential to revolutionise medicine and public health. The pace of change in this area is rapid and a clear strategy is needed to ensure that opportunities are not missed. This document sets out the Welsh Government's plan to create a sustainable, internationally-competitive environment for genetics and genomics to improve health and healthcare provision for the people of Wales.

In its 2016-2021 strategic plan, 'Taking Wales Forward'ⁱⁱ, the Welsh Government highlighted that it will place a focus on health at the heart of everything it does. It announced plans to increase investment in facilities and digital technologies to reduce waiting times and speed up the diagnosis of illness. It also announced plans to invest in training NHS staff and support good relations with industry in the interests of staff and patients. The Genomics for Precision Medicine Strategy will show how these plans will be fulfilled in the fields of genetics and genomics, supporting the delivery of precision medicine in NHS Wales. However, it is clear that patient benefits in this field will not be delivered by the NHS in isolation. Links to research and industry activities are more important than ever, and the wider ecosystem for genomics must be aligned to maximise health and economic benefits for Wales.

In March 2016, the Welsh Government published a Statement of Intent (Sol)ⁱⁱⁱ outlining the key principles that would underpin the development of a Genomics for Precision Medicine Strategy. The Sol noted the intention to:

- Develop internationally-recognised medical and public health genetics services – that are innovative, responsive and well-connected to the major genetics and genomics initiatives that are evolving worldwide.
- Develop internationally-recognised research in genomics and excellent platforms for precision medicine, with All-Wales leadership and coordination and strong links to clinical genetics.
- Be outward-looking, and actively seek out partnerships that can strengthen genomics and precision medicine services and research in Wales, with a focus on those partnerships that will bring the biggest benefits for patients.
- Develop the NHS and research workforce, in recognition that this investment will have the biggest impact on our ability to realise the potential of genomics and precision medicine for patient benefit.

Significant progress has already been made against these key aims. Wales has recently joined the 100,000 genomes project and is establishing a strategic partnership with Genomics England, having successfully obtained £1m funding from the Medical Research Council and £2.4m funding from the Welsh Government. The new funding will help to build genomics capacity (in terms of expertise, technologies and facilities) in Wales and lead to the establishment of a Genomic Medicine Centre in Cardiff. It will provide an opportunity for Welsh patients with rare diseases to take part in the 100,000 genomes research programme, with the potential to receive more accurate and quicker

diagnoses. The funding will also support a scoping exercise to identify the requirements for linking genetic and genomic data to the Welsh Secure Anonymised Information Linkage (SAIL) databank.

This Strategy focuses on developing genetics and genomics capabilities, because these technologies are becoming increasingly affordable, already having a major impact on precision medicine and transforming the management of infectious diseases. In precision medicine, genomic technologies enable more precise diagnoses or prediction of diseases and response to therapy so patients can be treated in a more individualised way. In infectious diseases, genomic technologies are providing more detailed pathogen identification to underpin epidemiological investigation of outbreaks, prediction of antimicrobial resistance, characterisation of virulence factors and determination of responses to therapy and disease transmission^{iv, v, vi}. Genomic technologies alone will not be sufficient to deliver precision medicine and public health. Other high throughput molecular diagnostic approaches “omics” and advanced therapies (e.g. regenerative medicine) will play an important role in the future of precision medicine, but are not the focus of this Strategy.

Co-production – working with patients and the public in genomics

Prudent healthcare highlights the importance of co-production (citizens and professionals sharing power and working together in equal partnership) for NHS Wales. It is vital that the public are aware of new innovations and challenges in the field of genomics and empowered to make informed choices regarding their health care needs. Patients and the public in Wales have supported the development of this Strategy and will play a key role in its implementation.

The All Wales Medical Genetics Service will establish mechanisms of engaging with patients to drive service developments and will continue to capture patient experiences to improve service delivery. Charities and patient organisations will be key partners in the development of information and support tools that are tailored to patients’ needs. Improving wider understanding of how genes and DNA influence our health, as well as how genomic services are organised and accessed in Wales will be a key part of the Strategy. This is important to support both the public and professionals in understanding service developments, taking an informed part in decisions about technological advances and, importantly, understanding the public health implications of genomics. With improved understanding of genomics the public, professionals and policy makers can be genuine partners in developing the research and engagement agendas around the ethical, legal and social implications of this technology.

Building on the Wales Gene Park existing programme with schools and colleges will support understanding and knowledge exchange among young people. Wales Gene Park will continue to promote genetic literacy through a variety of media to reach wider audiences and engagement activities will raise general public awareness of genomics and career opportunities in genomic medicine.

The citizens of Wales have shown themselves to be extremely forward-thinking and supportive of research, and initiatives such as the Wales Cancer Bank have demonstrated very high proportions of patients are willing to take part in research studies. We will ensure that patients and families have the opportunity to be partners in identifying research priorities, developing research proposals and contributing to research governance in genomics research. HealthWise Wales is a new initiative

which epitomises this approach. Set up to allow everyone in Wales to play a role in determining the most important priorities for research in health and social care, HealthWise Wales is a cohort of the Welsh population who have donated their own health and lifestyle information. Governed by members of the public for the population of Wales, this provides a key platform for research.

Large data sets are an essential tool to identify the genetic and genomic causes of disease and response to treatment and will underpin precision medicine. However, genomic data brings specific challenges with respect to anonymisation and it will be important to enable patients and the public to contribute to the development of appropriate information governance systems. The Welsh Government is committed to an open, transparent and publically agreed approach to the generation, storage, analysis and, sharing of such data.

1. The Wales Gene Park and the All Wales Medical Genetics Service will work with the citizens of Wales to support the development of an open, transparent and publically agreed approach to the sharing of genomic and precision medicine data for service development and research.

Clinical and Laboratory Genetic services

The first human genome sequence was completed in 2003, and this was followed by a period of rapid development of the understanding of the role of genomic variation in human disease. Coupled with advances in the technologies underpinning genetic research, this enabled notable new interventions which are now applicable in the clinical setting. In 1990 the genetic basis was understood for fewer than 2% of the estimated 7,000 'rare' diseases (conditions occurring in fewer than 5 in 10,000 people); in 2013, approximately 50% of inherited conditions had a known molecular basis, and it is predicted that most of the remaining disease-causing genes will be identified by 2020.

The development of new genetic technologies such as next generation sequencing (NGS) and the falling costs of genomic analysis have enabled their increased use in disease prediction, diagnosis and management of common disorders and the management of families with specific rare genetic disorders. Genomic advances are aiding the understanding of the nature of cancer, the variability of individual responses to drugs (pharmacogenomics) and the genetic determinants underlying common complex conditions, such as heart disease, psychiatric disorders and diabetes. Underpinning precision medicine, genomic knowledge is increasingly relevant to all healthcare practitioners.

The demand for genomics and genetics for precision medicine services is anticipated to expand greatly over the next decade. Whilst these services are currently requested by a highly specialised group of clinical teams, it is expected that the use of genomic services will become routine in many different clinical areas.

The case for Wales

Wales is well positioned to take advantage of genomic developments. The All Wales Medical Genetics Service is the single provider of NHS laboratory and clinical genetics services in Wales. The service has strong links across the UK, having led on the UK implementation of specific patient

pathways, the delivery of specialist UK genetic testing network services and the development of genetic precision medicine services in oncology.

The Clinical Genetics service is organised as a hub and spoke model, with hubs based in Cardiff, Swansea and North Wales, these deliver genetics clinics across Wales. In addition to organising tests and supporting the interpretation of results, the clinical service provides genetic counselling that plays a vital role in enabling patients and their families to make informed choices regarding their care needs. An efficient, joined-up approach has enabled the clinical and laboratory service to work together with Third Sector organisations to deliver innovative services for Wales, such as the familial hypercholesterolaemia cascade testing service.

The relatively small size of Wales and its single Genetics service has enabled the development of efficient relationships and service delivery models. The All Wales Genetics laboratory is one of Cancer Research UK's (CRUK) Stratified Medicine Technology Hubs and is regarded as one of very few UK centres of excellence in this field. The laboratory was instrumental in the development of centralised genomic solid tumour services, in close collaboration with the Velindre Cancer Centre. A similar service model is now being adopted in England and there are opportunities to adopt it across other services in Wales, e.g. through co-location of genomic facilities and expertise for All Wales Medical Genetics Service, Public Health Wales and the Welsh Blood Service.

The Public Health Wales Microbiology Service provides diagnostic and clinical services to most of the health boards and trusts in Wales via a network of laboratories across Wales. It also provides support to Health Protection Teams, health board and trust infection control programmes and regional and national surveillance programmes. Welsh Blood Service has existing capabilities in genomics through the Wales Transplant and Immunogenetics Laboratory and is developing these further, in particular, to support the development of cellular treatments where there is increasing cross-over with genomics. Although the major focus of this Strategy is the development of genomics capabilities to underpin precision medicine, Wales will seek to develop links between genomics and other fields, such as regenerative medicine, veterinary sciences and environmental monitoring. Close links will be established between Cell and Gene Therapy Strategy (currently under development by the Welsh Blood Service and Welsh Government) and other Government Departments; this will ensure maximum value is realised and wider drivers of the technology are considered.

Approach in Wales

Genetic and genomic services for precision medicine will continue to be delivered on an all Wales basis, with an emphasis on providing equitable access for patients across Wales to excellent and efficient services. Building appropriate service capacity and capability for the future will require consolidation of existing partnerships within and beyond Wales and the development of new collaborations for IT and data-links, training capacity, research and with industry.

The All Wales Medical Genetics Service lead in the development of standard protocols (e.g. for consent and data use) and in the accurate interpretation of genetic and genomic data. All Wales Medical Genetics Service will work with collaborators and national and international initiatives to manage the ethical, societal and legal issues associated with genomic analysis and apply best

practice in consent, interpretation and the feedback of results to clinicians and patients. A flexible approach to incidental findings will be prioritised^{vii}.

Genomic Multi Disciplinary teams will be required, with participation from the relevant specialty, clinical genetics and AWGL/bioinformatics, and the delivery of this will have significant workforce and IT infrastructure requirements. The role of the Clinical Geneticist and Genetic Counsellor will remain critical to this model, as these are key elements in providing a good patient experience, in addition to good health and wellbeing outcomes. The nature of genes and DNA means that changes which affect health can be passed-on between generations or be present in other family members. The choices that are made in genomic testing are complex, and clinical services play an important role in supporting patients and their families to understand these complexities and help them make the right decisions. Genetic counsellors also play a key role in supporting other healthcare professionals, particularly in the interpretation of unusual cases (e.g. rare diseases).

Looking forward, services will be prioritised based on clinical need and Welsh expertise. Our strategy is to release funding for genomic investigations through the substitution of more costly investigations, or the cost-avoidance of treatments where these will be ineffective or harmful. New genetic or genomic tests will continue to undergo full appraisal for clinical utility prior to introduction into NHS Wales services, to confirm their clinical benefit and cost effectiveness prior to broader adoption and implementation. As the sole Genetic service in Wales, new tests are appraised through UK mechanisms which are then endorsed in Wales before adoption. Tests fall into two categories:

1. For rare genetic disorders, new tests are approved by the UK Genetic Testing Network (<https://ukgtn.nhs.uk/>) through the submission and critical appraisal of a gene dossier. Recently it has become common for genomic tests to be approved.
2. For common and precision medicine services, new tests are approved by National Institute for Health and Clinical Excellence. New treatments are also approved that require an associated genetic test.

The implementation of genomic technologies, molecular diagnostics and eventually, point of care tests, within NHS Wales will require a supporting quality assurance and governance framework. The All Wales Medical Genetics Service will work with the NHS Wales Directors of Therapies and Health Sciences to develop this through the implementation phase of this Strategy.

All Wales Medical Genetics Service will work with the All Wales Medicines Strategy Group (AWMSG) to develop a policy position for medicines where a genetic test indicates the selection of an agent (e.g. oncology), and the Health Technology Wales for the clinical and economic appraisal of other new genetic and genomic technologies.

Genomics has the potential to have a profound impact on traditional pathology disciplines. The All Wales Medical Genetics Service and the genomics taskforce, which is responsible for delivering this Strategy, will work closely with national pathology groups to link this work with wider developments in the pathology modernisation programme. This will support the development of integrated diagnostic and precision medicine clinical pathways to create more efficient and sustainable services for patients.

Genomic services in Wales should not be delivered in isolation. Links with services in the UK and beyond are essential for data sharing, training, and technology development. Welsh scientists, clinicians, counsellors and researchers should remain embedded with UK initiatives such as the 100K Genomes Project and the CRUK Stratified Medicine programme so that they have the opportunity to translate knowledge and skills into services in Wales. Welsh Genomic services will work to at least the same standard as the UK Genomic Medicine Centres, Genomic Central Laboratory Hubs and Public Health England and will aspire to be a leader within a coordinated UK network.

Priority 1 – Hosting and commissioning of All Wales Medical Genetics Service

There are a number of characteristics associated with the All Wales Medical Genetics Service that suggest a bespoke response is required to support the development of the service in future. The strategic significance of the service to Wales cannot be overstated and a small, specialised and rapidly developing service needs to be nurtured and supported. The rapid development of specialised genetic tests for cancers and rare diseases presents an immediate and continuing challenge to commissioners and providers in keeping pace with new advances. Mainstreaming of genetic services across a wider array of clinical areas is also rapidly gaining pace.

The current and future potential of genetics services are poorly understood outside the specialist field which limits the ability of the NHS in Wales to fully exploit the possibilities and creates risks for the international competitiveness of Welsh Health Services in future. The service requires stronger arrangements for both commissioning and service provision if the ambitions within this strategy are to be realised.

The Welsh Health Specialised Services Committee currently commissions the All Wales Medical Genetics Service through a single service specification and the current services are relatively small and highly specialised. The clinical and laboratory services are both currently provided through CVUHB under direct management arrangements. Commissioners have to balance investment in genetics with other service pressures and likewise the provider has to balance service pressures in the clinical and laboratory services with other operational pressures and strategic priorities. The specialist nature of the genetics service means that engagement with the service by other Health Boards and Trusts is limited other than through the shared commissioning model and the hosting of outreach services.

Moving forwards, it is imperative that the service in Wales develops in a coordinated way to avoid the piece-meal development of local services that will compete for resources and specialist expertise. This means supporting strong links and seamless working between the clinical and laboratory service components of the All Wales Medical Genetics Service, and ensuring that they have strong and coordinated management. As demonstrated by successful genomics services across the UK and beyond, the service needs high quality premises and to be consolidated into one location, to enable it to attract investment, support linkage with genomics activities in other parts of NHS Wales and maintain parity with developments across the rest of the UK. It is clear that in the future genetics and genomics will be everybody's business and it is essential that all Health Boards and NHS Trusts in Wales are fully involved in the development and the provision of the service in future. It is also imperative that the commissioning and management of the service is designed to support pure and translational research and the formation of strategic partnerships.

Priority 2 - IT infrastructure requirements

The IT issues surrounding the delivery of current and future genomic services are numerous. Many are already acknowledged at an all Wales level and the genomics for precision medicine agenda needs to be engaged. Wales requires a significant increase in IT and bioinformatics capability and support to enable the handling and analysis of genomic data. The full value of genomic data for individuals is only realised when it is shared with massive data sets and it is therefore imperative that the Welsh genomic data can be shared with NHS England and other non-NHS initiatives.

As genomics is mainstreamed for precision medicine, service users throughout Wales will require easy and rapid access to genetic and genomic tests. Future patient management systems for NHS Wales need to be paper-free and able to operate within an all-Wales system that can export/import analyses from/to Wales electronically. This requires the engagement of All Wales Medical Genetics Service with all Wales NHS and IT digital programmes, and also dedicated IT staff within All Wales Medical Genetics Service to support participation. Within Welsh Government, cross talk between the Genomics for Precision Medicine Strategy and the Digital Strategy implementation groups will underpin these activities. Furthermore, the All Wales Medical Genetics Service and the Genomics Taskforce will work with partners such as NHS Wales Informatics Service, The Office for National Statistics (Data Science Centre) and Super Computing Wales to support the development of strong IT capabilities for genomics.

Priority 3 - Estates requirements

The All Wales Medical Genetics Service will operate as a single joint Clinical and Laboratory service, with one adequately sized laboratory suite and clinical hub, and outreach clinics across Wales. Ideally, the service will be co-located with both the Public Health Wales genomic clinical and laboratory service and the Wales Gene Park, to enable sharing of genomic, bioinformatics and IT facilities, expertise, and knowledge. The clinical service needs to have guaranteed and dedicated space for regular clinics at hospitals across Wales and dedicated facilities for local staff based at these hospitals.

The pace of change is such that it is difficult to predict the exact requirements for technologies and facilities more than a few years in advance. Given the potential for change, a dynamic and phased approach will be required. In the short term, the All Wales Medical Genetics Service, Cardiff and Vale University Health Board and Welsh Government will work in an open and transparent manner to identify estates for the All Wales Genomics Laboratory. Longer-term plans will be developed for funding to support cutting edge facilities that are fit for purpose and the expected expansion, and consider the requirements of partner organisations, NHS Wales Health Boards and Trusts. Building on existing developments, smart and automated laboratory solutions will be necessary to support growth and enable decreased costs of analyses.

Priority 4 - Provision of clinical services

Existing types of genetic analysis include the detection of known mutations, screening of single genes or panels of genes and analysis of large-scale genomic changes. For many patients these will still be relevant and will continue to be provided. However, it is now possible to analyse all genes simultaneously, so clinical services will now provide genomic analysis; through clinical exome

analysis (those ~7000 genes known to be associated with human disease), whole exome analysis or whole genomes. The use of gene panels (10-500 genes) is highly relevant in cancer and for those conditions associated with multiple but specific genes. The clinical utility and requirement for pharmacogenetic testing is anticipated to increase in the near future. WHSSC will extend its commissioning of capabilities and work with All Wales Medical Genetics Service to predict future requirements to enable a range of specialties to access genetics and genomics analyses in line with expected demand.

2. WHSSC will retain a specialist national commissioning model for All Wales Medical Genetics Service that is fully engaged with all Health Boards and NHS Trusts. It will develop a commissioning strategy that is nimble and responsive to rapidly changing demands for genetic, genomic and precision medicine services for a range of clinical specialties. Welsh Government and WHSSC will work with All Wales Medical Genetics Service to predict the future requirements for genetics, genomics and precision medicine services and will consider a protected development fund to enable to timely adoption of new capabilities/services.
3. The Welsh Government will work with CVUHB to further develop the All Wales Medical Genetics Service as an All-Wales Service. Mechanisms will be developed to include NHS Wales Health Boards, NHS Trusts, Welsh Health Specialised Services Committee and other key partners in governance and oversight structures for All Wales Medical Genetics Service, to ensure that it fully reflects All-Wales service, teaching and research interests.
4. Welsh Government will convene key stakeholders, including NHS Wales, NHS Wales Informatics Service, All Wales Medical Genetics Service, Wales Gene Park and HEIs in Wales to develop a strategy for networking capability to support the transfer of genomic and precision medicine data. This will include the capability to receive and send patient and sample data within Wales, out of Wales and with academic and commercial partners. It will also seek to understand the distinctive Information Governance requirements associated with sharing and linkage of genomic data, and ensure that a clear, transparent approach is designed in co-production with the Public.
5. A business case will be developed in year one for short and long-term accommodation solutions for a genomics laboratory suite with sufficient capacity for future growth and ability to accommodate the requirements and genomic facilities of partner organisations.

Research and Innovation

Research and innovation in genomics is a global endeavour that is taking place at a massive and expanding scale. It is fast moving and highly competitive. None-the-less, and despite Wales' small size, there are a number of specific fields of genomic research where Wales is internationally competitive. Supporting and building upon these areas of excellence is likely to be effective in attracting new investment from public, commercial and third sector sources, enabling external collaboration with high quality partners. It will also enable Wales to attract top-quality researchers, linking in with the Welsh Government's Sêr Cymru programme.

The case for Wales

Relevant existing areas of research excellence in genomics and precision medicine include:

- Cardiff University's Medical Research Council Centre for Neuropsychiatric Genetics and Genomics. This brings together internationally acclaimed researchers who investigate the causes of mental health problems with a focus on psychoses, neurodevelopmental disorders and neurodegenerative disorders.
- The Institute of Medical Genetics. Here, clinical and non-clinical academics from Cardiff University and the clinical and laboratory staff of the All Medical Genetics Service create a focus for translational genomic research into specific rare diseases and cancer.
- Cardiff University's Systems Immunity Research Institute where researchers apply a range of "-omic" technologies to develop precision approaches to diagnosis and monitoring of infections and chronic inflammatory disorders and for personalised cancer immunotherapy.
- Swansea University Medical School's Asthma and Allergy Group that is part of a collaborative of UK expert centres identifying biomarkers for stratification and better targeted treatment of asthma.
- Swansea University Medical School's Neurology and Molecular Neuroscience Research Group that is determining the genomic architecture of epilepsy and other neurological disorders through international collaborations.
- The CLIMB (MRC Cloud Infrastructure for Microbial Bioinformatics) bioinformatics facility has been established by researchers from Swansea and Cardiff Universities, together with collaborators in Warwick and Birmingham, to develop and deploy a world leading cyber-infrastructure for microbial bioinformatics.
- Bangor University's Centre for Health Economics and Medicines Evaluation, which leads in Wales on the economic assessment of health technologies and pharmacogenetic tests.

The Genomics Policy Unit at the University of South Wales, has more than two decades of research experience in health professional education, competence and workforce development in genomics and in the public understanding of genomics, particularly in young people. There are also other areas of research excellence in Wales that lie outside the domain of precision medicine but that contribute to the wider base of genomics technical expertise. For example, the Plant Genome and Chromosome Biology Group at Aberystwyth University's Institute of Biological, Environmental and Rural Sciences have expertise in genomics and bioinformatics and is a member of the All Wales Next Generation Sequencing Network.

Together, these groups constitute a "network of excellence" that underscores the quality of the Wales brand in genomic medicine. There is a need to support these areas and this overarching strategy should inform those of HEIs, Health and Care Research Wales and the NHS.

Wales has implemented a number of significant research biobanks comprising NHS patient samples and linked clinical data. These include the WCB, National Centre for Mental Health (NCMH) biobank, Wales Dementia Research cohort and the Swansea Neurology Biobank. Wales has also recruited participants to the UK Biobank and from 2017 will recruit Welsh patients to the UK 100,000 Genomes Project. The HealthWise Wales project will offer an opportunity to investigate genetic/biological and environmental factors together in a Welsh context.

Many more focused or disease-specific research sample collections have been and are being assimilated by researchers in Wales. Some comprise samples from NHS patients or healthy individuals exclusively from Wales while others include samples from patients originating across the

UK or internationally. The development of mechanisms for optimising the use of these resources, for sharing the data arising from them for secondary research and for linking to genetic / genomic data is a strategic need. Such mechanisms will need to be acceptable to the public.

Approach in Wales

Priority 1 - Integrating Current Infrastructure

Much of the existing research infrastructure for genomics in Wales has been developed opportunistically with strategy being determined at the level of single institutions or smaller units. A higher-level approach for integrating genomics infrastructure is provided through the Wales Gene Park, which has been developed as a Health and Care Research Wales Infrastructure Support Group.

Laboratory platforms for genomics, transcriptomics and epigenomics research are established in Wales, mainly in Cardiff (including a facility shared between the All Wales Medical Genetics Service and Wales Gene Park and Aberystwyth (mainly used for non-medical plant genomic applications). Much NGS for research is outsourced, either to commercial providers on a fee-for service basis, or for sequencing at major genomics centres through national or international research consortia.

Wales Gene Park has initiated the All Wales Next Generation Sequencing Network covering genomics platforms and bioinformatics support at Aberystwyth, Bangor, Cardiff and Swansea Universities. This provides a forum for those involved in next generation sequencing provision to better plan and share technology platforms and expertise with the aim of enabling wider and better informed access to next generation sequencing technologies for researchers in Wales. While it has been unnecessary and unrealistic for Wales to develop next generation sequencing facilities on the scale of major sequencing centres, the continuously falling cost and increasing robustness of next generation sequencing is making easy, local and flexible access to the technology an everyday requirement for biomedical sciences.

Wales' participation in the UK 100,000 Genomes Project will be underpinned by the development of the Wales Genomic Medicine Centre, which will also act as a focus for the translation of genomics research into NHS Wales. The Wales Genomic Medicine Centre will work closely with the Wales Gene Park, All Wales Medical Genetics Service and LHBs and Trusts across Wales and will be strongly aligned with Genomic Medicine Centres established in participating UK regions. Initially, the Wales Genomic Medicine Centre will recruit patients from across Wales with rare diseases who stand to benefit from precise genomic diagnosis through research-based whole genome sequencing provided by Genomics England. Genetic variants that appear likely to be causative will be interpreted by Wales Genomic Medicine Centre and confirmed for NHS Wales by All Wales Medical Genetics Service. Laboratory, clinical, bioinformatics and health informatics staff from the NHS and HEIs across Wales will work to achieve wide integration of genomic data from the project in patient care. Welsh researchers will also contribute to and exploit the project's resource of UK genomic and linked clinical data for research through membership of GeCIPS (Genomics England Clinical Interpretation Partnerships). Opportunities to extend the partnership with Genomics England to other groups of disorders such as cancers may develop subsequently.

Supporting innovation in diagnostics will be critical to ensure that the benefits of basic genomics research are translated into faster, more reliable diagnosis and better treatment selection for

patients in Wales. It is also important to support activities to demonstrate the health and economic value of implementing novel technologies and enable a strong case to be built for widespread adoption. The Welsh Government will continue to provide support for NHS innovation and collaborative research with diagnostics and pharmaceutical companies, using innovative procurement mechanisms, targeted support for technology development and adoption and outcomes focussed partnerships. Coordination and oversight in this area will be underpinned by activities described in 'Strategic Partnerships' below, to ensure a joined-up, All-Wales approach and alignment with the aims of the Strategy.

Priority 2 - Information Technology

Genomics is characterised by large datasets that create significant IT demands in terms of hardware, networks, staff, security and governance. Research data may be generated locally or may be imported from external providers or the NHS. Research and NHS IT needs for handling large data sets overlap and there is a mutual need for secure sharing of data. Although highlighted by immediate needs in genomics, these requirements are generic and extend beyond genomics to other areas of precision medicine. Work is already underway and must continue, with the Wales Gene Park working with Higher Education Institutions and the NHS to develop integrated Next Generation Sequencing, bioinformatics and IT platforms and proposals for a joint data-sharing and IT strategy for genomics and precision medicine.

Priority 3 - Clinical Data for Research

Strong NHS services create opportunities for NHS staff to support and lead research and enable effective translation of research findings into clinical practice. Clinical and laboratory NHS services can help to identify research questions and priorities by recognising unmet needs. They provide major opportunities to recruit patients to research and can also play lead roles in translational research programmes. The All Wales Medical Genetics Service has long-established relationships with non-NHS partners, including Cardiff University's Institute for Medical Genetics and the Wales Gene Park, with which it shares genomic facilities, resources, expertise, knowledge and educational programmes. This strong collaborative partnership has been critical for the successful service translation of research findings. The All Wales Medical Genetics Service partners in several initiatives such as:

- Wales Cancer Partnership
- Wales Cancer Research Centre (WCRC)
- Wales Cancer Trials Unit (WCTU)
- Wales Cancer Bank (WCB)
- Centre for Trials Research (Cardiff University)
- CRUK Experimental Cancer Medicine Centres (ECMC).

The All Wales Medical Genetics Service has supported several UK clinical trials in oncology which have directly led to successful service translation. Access for NHS staff to training in genomics and precision medicine and protected research time (for example through the Health and Care Research Wales Clinical Research Time and Research for Public and Patient Benefit awards and in job planning) are essential to the NHS optimising its contribution to research in Wales.

The provision of the vast majority of healthcare in Wales via the NHS creates an excellent opportunity to gather comprehensive clinical and laboratory health data on the Welsh population. In Wales, as in most countries, the ability to generate high quality high throughput molecular “-omic” data for research is not yet matched by an ability to assimilate linked high quality clinical and outcome data from across all clinical databases, but significant progress is being made. The SAIL Databank held at Swansea University brings together routinely collected public sector data on the Welsh population, including health data, for research. Inclusion of genomic data in SAIL has the potential to create a unique and powerful databank for research, but mechanisms for doing this while preserving anonymity require further clarification. A work-stream within the 100,000 Genomes Project in Wales will address this issue during 2017-2018.

Standardised, high quality clinical and outcome data is collected within specific research projects in genomic and precision medicine and clinical trials in Wales. Additionally, the All Wales Medical Genetics Service holds a large number of patient samples and associated genetic / genomic data. However, these are not readily available for wider, different or subsequent research use. Planning to obtain routine consent for All Wales Medical Genetics Service samples and for research samples to undergo genomic analysis in wider clinical research presents an opportunity to increase the reach and integration of genomics in health research.

6. The Wales Genomic Medicine Centre will be developed as a virtual centre, built upon close working between the Wales Gene Park and All Wales Medical Genetics Service. The Genomic Medicine Centre will support Wales’ involvement in the 100,000 genomes project and act as a focus for the translation of genomics research into NHS Wales.
7. As part of the 100,000 genomes project, the Wales Genomic Medicine Centre will work with SAIL to identify mechanisms for linking genomic data to health and other data held within the SAIL databank.
8. All Wales Medical Genetics Service and Wales Gene Park will work together to review models of consent within All Wales Medical Genetics Service and develop a proposal for routine research access to surplus clinical genetics samples and data, laying the foundations for a unique platform for precision medicine and genomics research. This work will be developed in collaboration with patients and the public and be informed by the principles laid down in the information governance project.

Workforce

Investment in genomics capabilities for precision medicine will only be a part of the solution in Wales. Our key knowledge-base and asset lies in the ability of the NHS and academic workforce to deliver genomics for precision medicine. The rapid advancement in genomic technologies coupled with the anticipated increase in demand for genomic services means that specialists and the wider workforce increasingly require training to understand, develop, apply and interpret genomic methodologies. It is only through providing this training and developing our workforce that the benefits will be realised for patients.

Work has already begun in this area with the recent announcement of Scientist Training Programmes posts in Genomic Science, Molecular Pathology, Bioinformatics and Genetic Counselling

and Higher Specialist Scientist Training posts in Genomic Science, Infection Science and Molecular Pathology and an MSc in Genomic Medicine. The Wales Gene Park also plays a key role in training academics and healthcare professionals.

However, further work is necessary to fully understand the requirements in Wales for genomic training. As genomics becomes more routine within additional specialties, the wider NHS workforce must be equipped with the necessary expertise and knowledge to understand the application of genomics throughout the clinical pathway. Therefore, a scoping and capacity modelling project will be funded to determine the training needs of both genetics professionals and the wider workforce. To deliver maximal benefits, workforce training will need to be usable and accessible to all, and the All Wales Medical Genetics Service will play a key role in delivering genomic training for non-genetic healthcare professionals.

The case for Wales

Wales' integrated healthcare system brings several advantages for workforce education, including:

- All-Wales organisations for leading and delivering genomics services which are accessible, flexible and responsive to new developments
- Strong links between the Welsh Government, Universities and Health Education Wales (Health Education Wales) to influence health professional curricula
- Dedicated support from Health and Care Research Wales to educate and engage with health professionals through the Wales Gene Park

Approach in Wales

Priority 1 – All Wales Medical Genetics Service workforce

Addressing the growing gap in provision of genetic counselling, Bioinformatics and Clinical Scientists across Wales via funded access to Scientist Training Programme Programmes and additional consultant clinical geneticist posts will be funded as these will be crucial to develop a highly skilled workforce and meet the increasing demands on the service. Much of the burden of increased genomic testing will initially fall on clinical genetics services, and funding will also be provided to support additional genetic counsellors. Formal training and investment in clinical leadership programmes for scientists is also essential. The commissioning and delivery of Higher Specialist Scientist Training programmes for future Consultant Clinical Scientists will support the provision of an optimal workforce.

To retain the best staff, the genetics service must be an attractive place to work and training provision must satisfy the needs of staff. Access to funded MSc and other high quality courses in Genomic Medicine will support on-going training needs and maintain continuing professional development. Linking with other UK organisations to deliver skill based education to genetics healthcare professionals and programmes to 'train the trainer' will maximise impact and drive development of a genomic medicine centred approach to future services across all disciplines.

Capacity and capability in bioinformatics is a bottleneck in both the NHS and academia in Wales. Demand for bioinformatics skills and support is expected to continue to grow because of rapidly increasing local data generation, the requirement for clinical services using next generation

sequencing, increasing importation of data from outsourced sample sequencing and increasing requirements for the development and application of novel pipelines for research and clinical applications.

Resources will be developed to establish a network of expertise between NHS Wales and Welsh HEIs within the field. This will not only benefit both healthcare and research sectors in terms of knowledge-transfer, it will also align with plans to share IT infrastructure and data resources, and provide a more attractive working environment for bioinformaticians. MSc bioinformatics courses will provide students with the bioinformatics programming and systems management skills necessary to support NHS services and research. In the NHS, Scientist Training Programme trainees in bioinformatics will be able to study whilst working part-time within the service to support capacity building.

Healthcare scientists have a significant leadership role to play in terms of expertise and delivering innovation within the field of genomics for precision medicine. Appointment of an internal training coordinator for the All Wales Medical Genetics Service will ensure that both internal staff and external healthcare professionals have the required access to resources, equipment, software and on-going training opportunities.

Priority 2 - Wider healthcare workforce

The Health Science Strategic Workforce Group has recognised the new needs for genomics in developing the 10 year workforce strategy, “The Science behind Prudent Healthcare” and will work with education commissioners to align cross-University collaboration on the delivery of education. This Group will be key in ensuring gaps in provision of genomics knowledge are identified and addressed. For example, the role of specialist pathology is expected to expand and tailored training in genomics, linking with activities at All Wales Medical Genetics Service and Wales Gene Park, will be required to meet demand. Healthcare professionals across NHS organisations and Primary Care clusters will require access to tailored training to ensure their knowledge and expertise is current. Transition planning in regards to up-skilling knowledge and expertise will be planned for and included in job specifications along with provision for continuing professional development in this rapidly developing field.

The wider workforce including clinicians, managers, nurses and all professional groups must have access to formal training programmes in genomic medicine. Access to funded MSc Genomic Medicine places and a variety of continuing professional development Continuing Professional Development opportunities will be required to support improved knowledge and understanding for the wider healthcare workforce. Other initiatives, including an engagement programme which focuses on GPs and junior doctors and a genomics roadshow, targeting specialties where genomics will have a significant impact in the short to medium term, will be developed. Genomics will also impact screening services, the activities of the Welsh Blood Service and Public Health Wales. Awareness raising and clinical training in the delivery of genomics services for these services will need to be developed and delivered.

The Wales Gene Park already plays an important role in delivering genetics and genomics training for healthcare professionals in Wales. The Wales Gene Park will work with NHS Wales to expand its education programme and continue to provide access to high-quality training.

Priority 3 – Recruitment and retention of NHS and academic genomics workforce

For the All Wales Medical Genetics Service to both deliver and support the genomics for precision medicine services described, it is essential that its workforce is nurtured and grown. Recruitment for the succession of retiring consultant clinical geneticists, genetic counsellors, and clinical scientists will progress in parallel with growth in the same staff groups, and the recruitment of bioinformaticians, is an essential requisite for the growing service. Recruitment and retention in microbiology, specialist pathology and other allied areas will be supported through close working with All Wales Medical Genetics Service and access to excellent genomics facilities. Through this Strategy and other initiatives, Welsh Government and NHS Wales will work to attract and retain staff and develop excellent local opportunities for personal and academic development.

Building research capacity is important for the translation of technological and scientific advances to clinical practice and is critical to the success of integrating genomic medicine into routine care in Wales. Through this Strategy, the Welsh Government, NHS Wales and HEIs in Wales will work to foster young clinical and non-clinical research academics and support the creation of tenure track and tenure positions in genomic medicine. By providing ongoing development of a strong genomics research infrastructure and strategic support for relevant areas of research strength in Wales, the Genomics for Precision Medicine Strategy will be essential to underpin recruitment and retention of high calibre research staff.

9. Welsh Government will work with NHS organisations to ensure that the genomics training needs of All Wales Medical Genetics Service, Welsh Blood Service and Public Health Wales are reflected in Integrated Medium Term Plans. This will include further Scientist Training Programme and Higher Specialist Scientist Training posts in genetic counselling, bioinformatics, genomic science, microbiology and molecular pathology and ST training posts for Clinical Geneticists, as required.
10. Working with Welsh Government, Health Education Wales, Local Health Boards (LHBs), NHS Trusts, national pathology groups, Clinical Leads, Directors of Therapies and Healthcare Science, and the Health Science Strategic Workforce Group, All Wales Medical Genetics Service will lead on a scoping and capacity modelling project to determine training needs of the wider healthcare and academic workforce in genomics. Building on the recommendations made, Welsh Government will work with Health Education Wales to ensure that appropriate training opportunities and programmes in genomics and precision medicine, such as part-time funded MSc Genomic medicine courses and Continuing Professional Development training, are available to NHS Wales staff.

Strategic partnerships

New partnerships and further development of existing partnerships between clinical services, academia, industry and patients and the public are essential if we are to realise the benefits of genomics for precision medicine in Wales. Strong, effective partnerships will speed up change, accelerate adoption and drive up quality outcomes for patients. They will support the advancement of life sciences in Wales and enable shared risk and decision making to achieve the five 'P's of precision medicine: prediction and prevention of disease; more precise diagnoses; targeted and

personalised interventions; and a more participatory role for patients [adapted from Improving Outcomes through Personalised Medicine^{viii}]. Working together to develop collaborations between the NHS and universities in Wales, with UK and international research initiatives and with industry also creates new opportunities for the Welsh economy.

The Case for Wales

The Welsh Government and NHS in Wales are committed to being 'open and ready for business'. Work programmes will be developed to make clear the terms on which Wales is prepared to engage, based on a supportive and co-ordinated approach that doesn't constrain existing or future relationships or stifle innovation.

In developing collaborative partnerships, Wales needs to play to its strengths, including:

- The 'right' size population, a relatively stable population and a population base that can support epidemiological research (including population cohorts) and healthcare evaluation and is attractive to others who want to work with the NHS in Wales, especially third sector organisations.
- A planned, vertically integrated healthcare system capable of making All-Wales decisions.
- All-Wales standards, shared services and national information systems.
- Wales' excellent reputation in some services and specific research activities, as outlined above.

In return, Wales can offer:

- A strong relationship between the health system and government.
- A focus on specific clinical and research areas of strength, for example, rare diseases, cancer/oncology and neuropsychiatric disorders.
- A strong track record of working with industry partners in areas of strength for service provision, clinical trials, technology adoption, and clinical education.
- Genomic analyses to support trials and research.
- Development and validation of molecular information, bioinformatics and clinical phenotyping technologies with NHS partners.
- Research for co-development of new technologies or products with HEIs.
- Data mining and linkage, where Wales could create a unique role for itself, building on the SAIL databank.
- Access to sequence data and a source of anonymised samples for research and industry collaboration.
- A single all Wales medical and laboratory genetics service that can facilitate rapid adoption.
- Opportunities for clinical synergy, for example, collaborative spaces.

Our approach in Wales

Priority 1 - A business strategy

Working with partners, a business strategy will be developed that understands what partners, especially industry, require and can offer. This will define the needs of partners, cognisant of an understanding of their strengths and weaknesses, and articulate the offer of each partner to others.

The Strategy will be built upon the importance of aligned objectives, and clearly define the commercial opportunity to be expected and the distinction between ‘customers’ and ‘partners’.

The business strategy will address intellectual property (IP) and data sharing issues. Industry representatives have confirmed that they would prefer to retain IP through a proportionate approach that recognises the respective contribution value of inputs and outputs by each party. The Strategy will seek to resolve other issues with data including patient consent (with informed intent), a need for secure portals, data safe havens for research, cross-border data sharing, and privacy, ethical, legal and societal implications. Many of these have been debated nationally and reports have been published that can inform discussions. Wales will continue to play a role in the global effort of identifying biomarkers and therapeutics and is well placed to lead on the use of biomarkers and alignment to therapy.

Additionally, the business strategy needs to incorporate a marketing and brand strategy, to underpin the long-term plan for workforce education and engagement and raise the profile of genomics in Wales. It will promote Wales’ reputation for offering graduates an opportunity to work in an environment providing significant and forward looking career development routes. It will tell everyone what we are good at, with supporting evidence; show off our clinical and scientific stars; and identify champions for these services in Wales. All those working in the NHS and universities have a role to play as well. As evidence of the collaboration we need to foster across our institutes, clinical leaders and researchers need to behave collectively and speak for Wales (“My health board can’t do this but this health board in Wales can”).

A communications strategy will be key to communicate the purpose of this strategy and set realistic goals about what can be delivered. We are probably a decade away from the transformational change that genomics for precision medicine can offer in many therapeutic areas and patient interest groups have been very clear about the need to be honest and realistic about delivery. This communications strategy will need to be developed in co-production with the public to ensure clarity over definitions and that complex messages are conveyed clearly and transparently to all stakeholders.

Priority 2 - A Framework Agreement for Industry Engagement

Prospective industry partners who want to work in Wales need a unified approach to conducting business in the UK including clarity about the processes for engagement, clear ground rules and an equitable approach. Structured agreements help, but industry partners do not always need a legal agreement. Wales will develop a Framework Agreement, as already successfully used in a range of public and private settings and from which key features can be derived^{ix}.

The first requirement is a clear statement of the Aim(s) of the agreement followed by objectives (for example, to exchange views; to improve communication and provide efficient, targeted and timely information; to enhance mutual understanding; to build on existing interactions; and to increase transparency – source: European Medicines Agency^x).

Next, the agreement will set out the benefits to be expected, that is, the convergence of interests (for example, sharing information and technology to promote innovations; leveraging financial or in-kind resources and expertise; influencing networks; providing access to valuable distribution systems

to achieve a shared goal; or access to populations or customers that each partner could not achieve on their own – source: Government of Ontario^{xi}). The agreement will also describe the general context for the partnership including the points of interaction and the legal and regulatory requirements on each, and any specific to the individual partners.

A set of universal and specific principles address the features necessary for successful partnerships. Universal principles, including voluntary participation, trust and transparency, fairness and inclusiveness, equal treatment and opportunity, mutual benefits and compliance with existing procedures, for example, those for procurement will underpin the development of the Framework.

The agreement will then describe clearly the scope of the interaction and reference the need for an implementation plan. This should be followed by a description of the working arrangements. Next the agreement should describe the risks and risk allocation, that is, the divergence of interests. The NHS in Wales will expect alignment with and a focus on public good and all partners will want to avoid any real or perceived conflict and reputational harm. Industry will also want to protect its commercial interests. A strategy for IP is an essential element of this section of the agreement.

Finally, the agreement will set out the means by which it is monitored, triggers for termination, processes for revision and review, and procedures for any advisory arrangements.

Priority 3 – Strategic coordination

To meet Wales' requirements strategic coordination and advisory services are required. Strategic coordination will bring together senior academics, clinicians, industry and third sector advisers to facilitate partnerships and co-ordinate engagement between academia, the NHS, industry and third sector to maximise clinical and laboratory service and business development for Wales within an agreed Framework. This will:

- Provide a single point of contact for industry, marketing services and expert business support for genomics and precision medicine in Wales.
- Undertake or commission evaluations and research technological and clinical developments in genomics and precision medicine.
- Translate evidence from health technology assessments and clinical research into policy options for Wales.
- Bring policy options to the attention of decision makers (health policy makers including Welsh Government and established committees, e.g. All Wales Medicines Strategy Group) and payers.
- Establish collaborations with universities, health systems, international organisations, government agencies, foundations and the third sector.

The wider landscape is already populated with a wide range of partners of interest to Wales that will be explored and, where appropriate, actively pursued. Demonstrating the importance of working as 'UK plc', key partners will include Genomics England, with its established mechanisms for industrial collaboration, the Innovative Medicines Initiative, Horizon 2020, Research Councils, third sector organisations, PHG Foundation, and advisory groups such as the National Screening Committee. Wales will also seek out other new partnerships, for example, commercial organisations with strengths in handling 'big data', analytics, modelling and algorithmic decision-making. This will be critical to fully realize the benefits of genomics for precision medicine in Wales.

11. The Welsh Government will develop the capability for strategic coordination for industry engagement in genomics for precision medicine in Wales.
12. A lead organisation will be appointed to work with partners (including All Wales Medical Genetics Service, Wales Gene Park, Public Health Wales, WCB, Welsh Blood Service, Life Sciences Hub, Health and Care Research Wales, NHS Wales, Health Technology Wales, HEIs and third sector organisations) to develop a business strategy and a model Framework Agreement for Industry Engagement in genomics for precision medicine.

Conclusion

Over the last six months, approximately 120 stakeholders from academia, industry, the third sector, the NHS and the public have attended a series of events across Wales. These events have informed the development of this Strategy. However, it is not, and should not be, a static document. Rapidly emerging technologies will mean that regular review will be required.

The genomics taskforce will establish an evaluation work-stream to identify and monitor the key outcomes and determinants of success. The group will monitor progress and publish annual reports against key actions highlighted in this Strategy. Patients, the public and clinicians will be important partners in developing this work-stream.

Over the first year (by September 2018) the Taskforce will work to deliver the following objectives:

- i. The development an agreement for governance and oversight structures for the All Wales Medical Genetics Service, to ensure that it fully reflects All-Wales service, teaching and research interests;
- ii. The development of a forward-looking commissioning plan for All Wales Medical Genetics Service;
- ii. The development of a short-term estates plan for the All Wales Medical Genetics Laboratory and a business case for capital funding to support the development of a new laboratory estate for the All Wales Medical Genetics Service;
- iv. The development of a proposal and series of recommendations around routine access to samples and data within the All Wales Medical Genetics Service for research purposes. This will include a review of the ethical, legal and social implications of any proposed changes;
- v. The development of an implementation plan for an organisation to lead on strategic coordination of genomics in Wales;
- vi. A paper with recommendations on the requirements of the wider NHS workforce for training and development in genomics;
- vii. A proposal for the development of networking capability to support the transfer of genomic data within and outside of Wales for clinical and research purposes. This will include a publically-agreed approach to information governance; and,
- viii. The development of a plan for monitoring and evaluating the implementation of the Strategy.

Project teams will be developed with the relevant partners to progress each of the objectives and these will report to the Genomics Taskforce. The Genomics Taskforce will retain oversight of the Strategy, supported by a programme and project manager.

A budget of £6.8m has been allocated for the Strategy, spread over five years, and this is distributed over the five key areas with an additional generic budget to provide overarching programme and project management support. The allocated budget for the first year is as below:

Co-production	£90,000	
Clinical and laboratory services	£1,146,000	
Research and Innovation	£10,000	(In addition to funds already awarded for the 100,000 genomes project in Wales)
Workforce	£80,000	
Strategic partnerships	£10,000	(funding for the early years of the strategy is for scoping work, and an increased budget in this area will apply in the later years of the strategy)
Generic support	£72,000	

This Strategy outlines the initial steps necessary to develop the genomics for precision medicine infrastructure in Wales and lays the foundations for the routine application of genomic technologies to support precision medicine approaches in Wales. In doing this, it enables patients and the public of Wales to benefit from better healthcare and underpins a bright future for the application of cutting-edge genomic technologies in NHS Wales.

ⁱ Welsh Government (2016). Statement of Intent for Genomics and Precision Medicine.

<http://gov.wales/docs/cabinetstatements/2016/Genomicsstatementofintenten.pdf>

ⁱⁱ Welsh Government (2016). Taking Wales Forward. <http://gov.wales/docs/strategies/160920-taking-wales-forward-en.pdf>

ⁱⁱⁱ Welsh Government (2016). Statement of Intent for Genomics and Precision Medicine.

<http://gov.wales/docs/cabinetstatements/2016/Genomicsstatementofintenten.pdf>

^{iv} http://www.phgfoundation.org/briefing_notes/305/

^v <http://www.bbc.co.uk/news/health-20314024>

^{vi} [http://www.clinicalmicrobiologyandinfection.com/article/S1198-743X\(16\)30395-0/pdf](http://www.clinicalmicrobiologyandinfection.com/article/S1198-743X(16)30395-0/pdf)

^{vii} <https://www.geneticalliance.org.uk/media/1924/patient-charter-genome-sequencing-what-do-patients-think.pdf>

^{viii} NHS England, (2016). *Improved outcomes through personalised medicine: Working at the cutting edge of science to improve patients' lives*, Leeds.

^{ix} Genomics England, (2015). *A Framework for Industry Engagement*. https://www.genomicsengland.co.uk/wp-content/uploads/2015/03/A-framework-for-industry-engagement_march2015.pdf

^x European Medicines Agency, (2015). *Framework for interaction between the European Medicines Agency and industry stakeholders*, London. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195081.pdf

^{xi} Health Canada, the Ontario Ministry of Health and Long Term Care, and The Healthy People and Communities Steering Committee's Multi-Sectoral Partnerships Task Group, (2014). *Public Health and Food and Beverage Industry Engagement: A Tool to Guide Partnership Opportunities and Challenges*, Ontario, Canada.