Scotland's Precision Medicine Summit: 10 September 2018

Outcomes

Executive Summary

Background

Precision medicine has been defined by the WISH Precision Medicine Forum[1] as '*the tailoring of medical treatment to the individual characteristics of each patient to classify individuals into sub-populations that differ in their susceptibility to a particular disease or their response to a specific treatment, allowing preventative or therapeutic interventions to be concentrated on those who benefit, sparing expense and side effects for those who will not*'.

Precision Medicine is a field that is growing in significance in both the Scottish and UK life sciences strategies, and the adoption of Precision Medicine has the potential to be transformational for Scotland in terms of both population health and economic growth.

The First Minister has been clear in her aim for Scotland to be a "world leader" in the field of Precision Medicine, an area which has been singled out in the last two Programmes for Government, firstly as "vitally important to Scotland's future health" in 2017/18 and as a key aspect of Scotland's innovation agenda in 2018/19. The concept of a Precision Medicine Summit was initially mooted by members of the international Steering Group which led the BEIS Science & Innovation Audit- *Precision Medicine Innovation in Scotland*[2], and was subsequently endorsed by the First Minister of Scotland, who agreed to host the Summit. The Summit, which was held on September 10th 2018, was co-chaired by Professor David Crossman (Chief Scientist – Health) and Professor Dame Anna Dominiczak (Vice Principal and Head of College of Medical, Veterinary and Life Sciences, University of Glasgow).

The aim of the summit was to bring together pre-eminent academic, industry, NHS, and Government leaders to identify how Scotland can cement and capitalise on the strengths and opportunities in precision medicine identified in the BEIS Science & Innovation Audit, which was used as a foundational document for discussions at the Summit, and recent work by the Scottish Science Advisory Council on medical genomics, and agree a shared narrative that will catalyse economic growth and sustained patient benefit for Scotland. A key purpose of the summit was also to signpost the best direction for further investment by Scottish Government and research, innovation, industry and enterprise funders given the context of past investment in this area.

The Opportunity for Scotland

A clear vision for Scotland was outlined by the plenary speakers, who included eminent international industry and academic experts, and public policy consultants SQW who summarised the game-changing opportunities for Scotland identified in the BEIS Science & Innovation Audit. These key messages form the basis of a shared narrative for precision medicine:

- Scotland has an impressive portfolio of precision medicine assets, across NHS, academic institutions and industry. The Scottish Government has already invested significantly in infrastructure (e.g. the Queen Elizabeth University Hospital) and technology (e.g. Scottish

[1] http://www.wish.org.qa/wp-content/uploads/2018/01/IMPJ4495_WISH_Precision_Medicine_Report_WEB.pdf

[2] Awaiting publication by BEIS. Embargoed copies were distributed to Summit delegates and are available on request.

Genomes Partnership, Stratified Medicine Scotland - Innovation Centre), and has committed to developing precision medicine and genomics through its successive Programmes for Government;

- Scotland has several key differentiators, including the world-leading strengths of our clinical research, high quality patient data, and a single integrated healthcare provider (NHS Scotland), with large cohorts of patients with chronic disease;
- Scotland has an opportunity to be a world leader in precision medicine, in line with the aim of the First Minister, and drive economic growth across the country. However, the opportunity is time-limited as other countries are now investing heavily;
- The global Precision Medicine market is forecast to grow from $43bn in 2016 to $134bn by 2025 (Frost & Sullivan), representing an opportunity for Scotland to benefit from increased productivity, jobs and economic growth;
- Precision medicine has the potential to deliver significant savings for the NHS in Scotland, estimated to be in the region of £70 billion over 50 years. However to realise these potential savings, we need address the challenges of adoption and invest in solutions for the barriers which exist.

<u>High level Action Areas</u>

- Scotland's 'shared narrative' for precision medicine should be cascaded across relevant organisations to help inform the best direction for further investment, and to ensure resources are aligned and used to best effect.

- Long-term success requires a 'whole system' view and working better together across Scotland. For example, by integrating Scotland's complementary regional strengths in data science and precision medicine to turn health data into early diagnostics and precision treatments; and piloting technologies in one region for benefit across the whole country.

- Create and utilise the next generation of clinical decision support tools that will be needed by clinical decision makers, by embedding AI and machine learning in digital pathology and radiology.

- Scotland's health data is a key asset but it is vital that we have a connected, inter-operable pan-Scottish network, rather than a fragmented approach. We also need to make uniform data available to industry in a safe and trusted way. A short-term investment in the four existing safe-havens and ensuring connected interoperability would leverage industry investment and increased UK funding to Scotland, and benefit patients, the NHS, academia and industry.

- Scotland should fully utilise existing infrastructure investments by considering the development of the 'Living Laboratory' pilot, identified as an opportunity in the draft BEIS Science & Innovation Audit- *Precision Medicine Innovation in Scotland*, for the adoption of new technologies e.g. pharmacogenomics, to demonstrate the economic value of precision medicine, benefit patients, make savings for the NHS, and expand Scotland's growing cluster of co-located PM-related businesses.

- There is a need to enhance genomic medicine in the NHS, for diagnosis of rare diseases and to ensure that precision medicine can be utilised in cancer treatment (and other chronic disease areas) as soon as possible.

- Continued consideration should be given to Scotland's 'front door' for precision medicine. Exemplar projects are already successfully showcasing Scotland's expertise and applicability of precision medicine, and have attracted global industry interest and presence. A "once for Scotland" gateway to 'Scotland's Ecosystem for precision medicine' provides a single entry point into Scotland to continue to attract collaborative partners and streamline connections/pathways to the constituent parts of the ecosystem for Precision Medicine across Scotland.

Operational Steps – overcoming barriers to success

Round-table discussions at the Summit identified a number of current barriers which require to be addressed to ensure success. A number of these are already being actioned.

- **Data standardisation, interoperability and digitisation.** Progress is already being made through the Digital Health and Social Care Strategy and Industrial Strategy Challenge Fund support for genomics, digital pathology, radiology/imaging and diagnostics, and the development of Digital Innovation Hubs. It is important that these are aligned and support Scotland's vision for precision medicine.
- **Public engagement, trust and consent.** Work is in progress to address these issues, including a review of information governance to ensure appropriately controlled access to/use of data by public and private sector organisations, as the Digital Health and Social Care Strategy is implemented and HDRUK programmes of work roll out across Scotland; the development of PPI standards currently being piloted; the possibility of using SHARE to enhance recruitment of patients into Precision Medicine research; and the dissemination of information from exemplar projects such as Precision Panc. However, it is important that these are aligned and support Scotland's vision for precision medicine.
- **Workforce Development and Skills.** The Summit recognised that capacity and skills across both the NHS and academic workforces will need to be enhanced to ensure effective and aligned collaborative working between the NHS, academia and industry.
- **Cultural and Process Change.** These crucial areas include developing a clear vision and supporting road map for Precision Medicine in Scotland, more collaborative working across Health Boards to drive forward a "Once for Scotland" approach to scaling up the adoption of Precision Medicine across the NHS, guidance around IP, and streamlining NHS procurement procedures and processes.

The Summit provided a forum for the sector to come together with one voice, to confirm the tremendous opportunities for Scotland and discuss the high level action areas that we now must take together. The time is right for Scotland to move from aspiration to implementation of precision medicine, and fully deliver the benefits to patients, the billions of savings to our NHS and the contribution to economic growth and job-creation that precision medicine promises.

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Outcomes

Presentations, round table discussion and key outcomes

Introduction

Scotland's Precision Medicine Summit was hosted by the First Minister and co-chaired by Professor David Crossman (Chief Scientist – Health) and Professor Dame Anna Dominiczak (Vice Principal and Head of College of Medical, Veterinary and Life Sciences, University of Glasgow) at the Perth Concert Hall on 10 September 2018. The First Minister gave the keynote address (attached) to open the Summit. The Cabinet Secretary for Health and Sport also attended and spoke at the end of the morning presentations session. The purpose and aims of the summit are at **Annex A** and the Programme and discussion themes at **Annex B**. 108 invitations were issued, around 70 were able to attend. Presentations made at the Summit are summarised at **Annex C**. Summary outcomes for the round table discussions are at **Annex D**. The Summit was informed by the draft BEIS Science & Innovation Audit- *Precision Medicine Innovation in Scotland* and by the emerging findings from the Scottish Science Advisory Council report into medical genomics.

Outcomes Overview

Precision Medicine is growing in significance in both the Scottish and UK life science strategies and, if the opportunities to develop and implement Precision Medicine a pan-Scotland basis are seized ***now***, has the potential to be transformational in terms of both health improvement and economic growth. Scotland already has a well-established ecosystem and supporting infrastructure for Precision Medicine, underpinned by world class clinical research, renowned expertise in genetics and other clinical disciplines, high quality patient data, a unified NHS, significant cohorts of patients with chronic diseases, a vibrant life sciences sector and a Government committed to change (including through references to Precision Medicine in successive Programme for Government). Fully embedding Precision Medicine across Scotland could have significant impacts on: avoiding unnecessary treatments while securing better patient outcomes; reducing health care costs as the population continues to age; deepening the partnership between the NHS, academia and industry; and on leveraging new global opportunities across a range of sectors, with a significant contribution to Scotland's sustainable economic growth. Building on existing infrastructure; enhancing data interoperability and digitalisation; developing the next generation of clinical decisions support tools with embedded AI; and the progressive spread of genomics and other omics across NHSS will be central to the successful widespread implementation of Precision Medicine in Scotland. To secure this, a number of issues will require further action as outlined below.

Further Actions

The draft BEIS Science & Innovation Audit- *Precision Medicine Innovation in Scotland* clearly articulated the game-changing opportunities and challenges for the further development implementation of Precision Medicine on a "once for Scotland" basis. These, and the need to seize opportunities *now* were reflected and amplified in the presentations from the plenary speakers as summarised at **Annex C** and set the context for round tables discussions on the 3 themes identified prior to the Summit (at **Annex B**). **Annex D** reproduces the written outputs from the table discussions, by theme, the key elements of which are summarised below.

1. Opportunities and Challenges for Healthcare Innovation and Economic Growth for Scotland: Barriers and Solutions

Realising Precision Medicine

The Summit recognised that there had already been considerable investment in infrastructure to support Precision Medicine in Scotland, which should be built on and consolidated as a whole system approach to enhancing and implementing Precision Medicine on a truly pan-Scotland basis. Key issues needing further action included:

- The need to maintain a clear brand, single shop window and single entry point into Scotland to continue to attract collaborative partners and streamline connections/pathways to the constituent parts of the ecosystem for Precision Medicine across Scotland.

- The need to balance generic/general approaches to promoting/enhancing Precision Medicine per se with specific approaches to developing its constituent parts eg certain –omics will develop over time and may require adjustments to infrastructure and capacity (increased laboratory utilisation).

- Further development and real world implementation of Precision Medicine through the development of the "Living Laboratory" pilot to demonstrate patient benefits and NHS cost savings, particularly in the field of pharmacogenomics. This was identified as an opportunity in the draft BEIS Science & Innovation Audit- *Precision Medicine Innovation in Scotland* as a means of addressing the key challenge of *translating* innovation into standard clinical practice. The Living Laboratory would have the following elements:

    - a state of the art clinical setting of sufficient scale, where innovation and adoption can be integrated and results scaled nationally;

    - supporting world-class capabilities around healthcare economics, data science, clinical pathways and rigorous evaluation of both the adoption process and the impact of new technologies;

    - demonstrate and evaluate the savings to the NHS through the implementation of existing Precision Medicine diagnostics;

    - accelerate the growth of the life sciences cluster by attracting and supporting the development of companies working in the Precision Medicine space (including diagnostics, medtech, CROs, data security and provenance, and health economics); and
    - improve medication safety and efficacy for stratified patient cohorts by demonstrating the beneficial economic and patient outcome impacts of pharmacogenomics in a way that can be scaled up nationally.

There will be opportunities to address these issues once the BEIS Science and Innovation Audit: Precision Medicine Innovation in Scotland has been published and the Scottish Scientific Advisory Council report on medical genomics has been presented to Ministers.

Data Standardisation, Interoperability and Digitalisation

The Summit recognised the wealth and quality of Scotland's health data underpinned by the CHI number and national and regional approaches to NHS Research Scotland (NRS) safe haven data storage and authorised retrieval, linked to tissue availability via the network of accredited biorepositories. There are opportunities to be gained from building on these strengths and through better integration between clinical and research data and data science capabilities, including machine learning and AI. Key issues needing further action included:

- Ensuring NHS and wider research involvement in the development of high performing digital infrastructure/platform to support data analysis, integrated health management and the development of digital phenotypes

- Addressing fragmentation of data systems and silo working across agencies by developing a framework to bring together capacity to work at scale on a pan-Scotland basis through more standardised approaches to data formatting and collection, and building on the important foundation of NRS safe havens

- Developing a clear policy approach to routes that access data, including clear rules of engagement for industry access to/use of data within safe havens.

Some opportunities already exist to address those issues, including the Digital Health and Social Care Strategy and Industrial Strategy Challenge Fund support for genomics, digital pathology, radiology/imaging and diagnostics, and the development of Digital Innovation Hubs.

Public Engagement, Trust and Consent

The Summit recognised that public understanding and trust were vital to the successful implementation of precision medicine in Scotland. Awareness raising (information, education and expectation management), consultation (insight into the public's views) and empowerment (co-decision making) of the public were therefore central to success. Key issues needing further action included:

- Consent, especially in relation to access to/use of data and development of digital phenotypes.

- Education and expectation management. Precision Medicine, and the involvement of the private sector and commercial innovation, would need to be described in a way the public could understand. By its nature, Precision Medicine would mean that new treatments for an individual/group of individuals would be of no benefit to others. It is important that this, and the wider benefits (financial and otherwise) of Precision Medicine in terms of avoidable treatments and withdrawal from some screening programmes, are not regarded as rationing or cost saving. Patient benefit/service improvement, including safer prescribing, should therefore be key public facing messages.

- Empowerment, through developing a national approach to public/patient engagement.

Some opportunities already exist to address those issues, including the chance to review information governance, to ensure appropriately controlled access to/use of data by public and private sector organisations, as the Digital Health and Social Care Strategy is implemented and HDRUK programmes of work roll out across Scotland; the development of PPI standards currently being piloted; the

possibility of using SHARE to enhance recruitment of patients into Precision Medicine research; and the dissemination of information from exemplar projects such as Precision Panc.

Workforce Development and Skills

The Summit recognised that capacity and skills across both the NHS and academic workforces would need to be enhanced to ensure continued effective collaborative working between the NHS, academia and industry. Key issues needing further action included:

- Capacity of NHS workforce to engage with and support collaborative working is constrained due to other pressures and, for clinicians, lack of contracted programmed activity time dedicated to research and innovation. Maintenance of the clinical academic workforce will be essential

- Increased demand for, but under supply of and lack of clear career pathways for, data scientists.

- Specific training for NHS workforce is needed in Precision Medicine and genomics

Cultural and Process Change

The Summit recognised that effective tripartite working between the NHS, academia and industry, a prerequisite for the successful implementation of Precision Medicine, was already generally well established in Scotland. As with other areas of health innovation, there were challenges around adoption and spread of new technology and treatments which, rightly, were subject to clinical efficacy and economic tests and, as appropriate, to procurement rules. Key issues needing further action included:

- Developing a clear vision and supporting road map for Precision Medicine in Scotland, with a focus on priority areas for attention (eg pharmacogenomics, metabolic and inflammatory disease).

- More collaborative working across Health Boards to drive forward a "Once for Scotland" approach to scaling up the adoption of Precision Medicine across the NHS.

- Streamlining NHS procurement procedures and processes for the approval of new medicines/treatments to accommodate innovative and tailored medicines/treatment that would not become universally available.

- Empowering clinicians to feel comfortable engaging with industry and academic partners on the development and adoption of innovations.

2. Integration of Precision Medicine into NHS Service Delivery – Collaborative Working between Health Boards, Academia and Industry

As noted above, the Summit recognised that effective tripartite working between the NHS, academia and industry was generally well established in Scotland. There were capacity issues impacting on sustainable collaborative working (picked up above under *Workforce Development and Skills)* and 3 other specific issues identified by the Summit for further development.

The Power of Exemplars

There are current examples (eg Precision Panc, Future MS and Lung Matrix trials) of how use case exemplars (using a vertically integrated value-chain based model) could support connectivity and integration. A wider programme of identification and selection of similar exemplars, through a competitive bidding process and impact-focused business case evaluation, could be developed to focus on a manageable number of tractable issues (avoiding "boiling the ocean" that a more diffuse approach might encounter). Use cases would not necessarily require to be defined by disease (eg the development of a pharmacogenomics-based precision medicine approach could cut across multiple clinical areas) although if some were disease-based both cancer and rare conditions were thought to offer tractable opportunities. Any such exemplars should be pan-Scotland in their configuration and approach.

Academic Health Science Networks (AHSNs)

A single or coordinated regional AHSN(s) could facilitate greater coordination, act as a magnet for inward investment, and enable IP to be retained in Scotland. It/they would need to be sufficiently well and stably funded, and have agility and decision making capability for example on what areas, projects or companies to target.

Intellectual Property

Intellectual property (IP) in a collaborative environment created particular challenges around exploitability and pay-back. Issues that require further consideration included: the need for clearer guidance on IP; IP sharing, particularly in relation to spin-outs; clarity around the IP benefits to the NHS; specific issues in relation to IP for biomarkers which might be inhibiting commercial success.

3. Additional/New Investment Needs and Potential Sources

The Summit recognised that significant past and current investment in Precision Medicine infrastructure and systems formed a solid foundation on which to build. Key issues needing further action included:

- Ensuring that the business case(s) for additional or new investment tells and sells Scotland's story and offer, is well defined, evidence-based, developed in collaboration with key partners to ensure a pan-Scotland/"Once for Scotland" approach, forward looking and aligned to Scotland's health challenges, able to leverage funding from other sources and demonstrate how the NHS would benefit both financially and through service improvement.

- Using exemplars/use cases (see above) to attract investment.

- Developing the (public sector) funding infrastructure to enable capital investment at scale, adopt a more strategic (as opposed to reactive) approach to funding, be more flexible/adaptable in the use of funds to ensure innovative ideas can be developed further, offer seed funding to facilitate industry/academic collaboration, provide incentives/reward for HEI involved in innovation, offer one source of advice to attract external investment and is flexible/responsive to different company bases to support both multi-national company collaboration and SME investment.

- Incentivising collaborative working eg by targeted funding conditional on levels of partnership working (threshold number of Health Boards, HEI and industry working together).

Scotland's Precision Medicine Summit: 10 September 2018

ANNEX A

Purpose of the summit

Precision medicine can be defined as the tailoring of medical treatment to the individual characteristics of each patient to classify individuals into sub-populations that differ in their susceptibility to a particular disease or their response to a specific treatment, allowing preventative or therapeutic interventions to be concentrated on those who benefit, sparing expense and side effects for those who will not. It is a field that is growing in significance within the context of both the Scottish and UK life sciences strategies, with the potential to add tangible benefits in both health and economic terms, and is one in which Scotland as a whole already has real strengths.

The summit will bring together pre-eminent academic, industry, NHS, and Government leaders to identify how Scotland can cement and capitalise on its world leading position in precision medicine and to agree a shared narrative that will catalyse economic growth and sustained patient benefit for Scotland. By engaging activity leaders from the NHS, academia and industry from Scotland, the UK and internationally, the summit will use the outputs of the BEIS Science & Innovation Audit - Precision Medicine Innovation in Scotland: Accelerating Productivity Growth for Scotland and the UK; the themes emerging from the Scottish Science Advisory Council work on a report on medical genomics; and experiences of developments in Scotland and elsewhere to inform a strategy for sustainable economic growth, productivity and health improvement through the implementation of precision medicine in the NHS in Scotland, building on our existing strengths and helping to meet one of the stated aims of the First Minister, as set out in the 2017/18 Programme for Government[1]. A key purpose of the summit will be to signpost the best direction for further investment by Scottish Government and research, innovation, industry and enterprise funders given the context of past investment in this area.

Expected outputs

Informed by the BEIS Science & Innovation Audit- Precision Medicine Innovation in Scotland, the work of the Scottish Science Advisory Council on Genomic Medicine and the context of current international research, the summit will aim to have the following outputs:

- Overview of the Scottish strengths and opportunities for accelerating further development and practical application of precision medicine in Scotland and any barriers to this aim
- Proposals for overcoming any identified barriers
- Indicative assessment of what new or additional investment might be required, over what time frame, and identification of potential funders (including possible funding streams under the UK Industrial and life sciences strategies)
- Identification of opportunities for international partnerships and collaborations
- Identification of how the outcome of the Scottish Science Advisory Council report into genomic medicine in Scotland can best interact with and contribute to the precision medicine agenda, and the most appropriate approaches for equipping Scotland with genomics platforms allowing genomics to be taken forward in a sustainable way

[1] "The development of the precision medicine sector is vitally important to Scotland's future health. It will revolutionise health care, allowing specific treatments to be tailored to the individual characteristics of each patient. Scotland has outstanding strengths in this area and we will continue to build on these to assist the commercialisation of world-class research in precision medicine and genomics sequencing"- source "A Nation with Ambition, the Government's Programme for Scotland 2017-18".

- Identification of how to integrate precision medicine, including genomics, with service development in NHS Scotland
- Identification of how to operationalise the outputs from the summit
- Inform the development of a shared narrative around the above for consideration by Scottish Ministers

Scotland's Precision Medicine Summit: 10 September 2018

Annex B

PROGRAMME

Timings	Item	Speakers
09.30	Registration and coffee	
10.00	Welcome	Co-chairs
10.05	Key note address	First Minister
10.15	BEIS Science and Innovation Audit: Precision Medicine Innovation in Scotland: Key Themes	Professor Dame Anna Dominiczak
10.30	International Perspective	Dr Victor Dzau, President, US National Academy of Medicine (video)
10.35	International Perspective	Peter Silvester, President, ThermoFisher Scientific
10.50	Economic Development & Growth Opportunities	Luke Delahunty, Director, SQW
11.05	The opportunity to combine regional strengths in data science and precision medicine	Professor Andrew Morris, Director, Health Data Research UK
11.20	Development of the next generation of clinical decision support tools	Dr Ken Sutherland, President, Canon Medical Research Europe Ltd
11.35	Scottish Science Advisory Council Report on Genomic Medicine	Professor Tim Aitman, University of Edinburgh Professor Andrew Biankin, University of Glasgow
11.50	NHS Perspective	Fiona Murphy, Director, National Services Division, NHS National Services Scotland
12.05	Precision medicine within the Life Science Strategy for Scotland	Dr Dave Tudor, Vice President GSK and co-chair, Life Sciences Scotland Industry Leadership Group
12.20 12.45	Panel Q&A session: Including: Impressions from the morning and aims for the afternoon	Co-Chairs. Cabinet Secretary for Health and Sport.
12.50	**LUNCH**	
13.30	Summary of morning discussion Introduction to round table session	Co-Chairs
13.45	Facilitated round table discussion (3 themes): • Opportunities for healthcare innovation and economic growth for Scotland : barriers, solutions • Integration of precision medicine into NHS service delivery – collaborative working between Health Boards, academia and industry • Additional/new investment needs and potential sources	Rapporteur at each table Each table spends 20 minutes on each bullet, discussion key points to be captured by rapporteurs
14.45	Feedback from tables and discussion	Rapporteurs. Speakers' panel
16.15	Summary and next steps	Co-Chairs
16.30	Close	

ANNEX C

Presentations summary

***Anna Dominiczak* – BEIS Science and Innovation Audit: Precision Medicine Innovation in Scotland: Key Themes**

Key assumptions:

- covers the whole of Scotland, builds on the combined excellence of the four major cities, NHS and universities
- We already have a well-established Scotland-wide Ecosystem for Precision Medicine, centred around the Stratified Medicine Scotland-Innovation Centre
- The combination of world class clinical research, high quality patient data, NHS Scotland as a single health care provider and large cohorts of patients with chronic diseases, differentiates Scotland from other life sciences clusters

Exemplars:

- SMS-IC: Ovarian, Oesophageal & Pancreatic Cancer;, Rheumatoid Arthritis; Multiple Sclerosis; IBD/COPD

Gap Analysis:

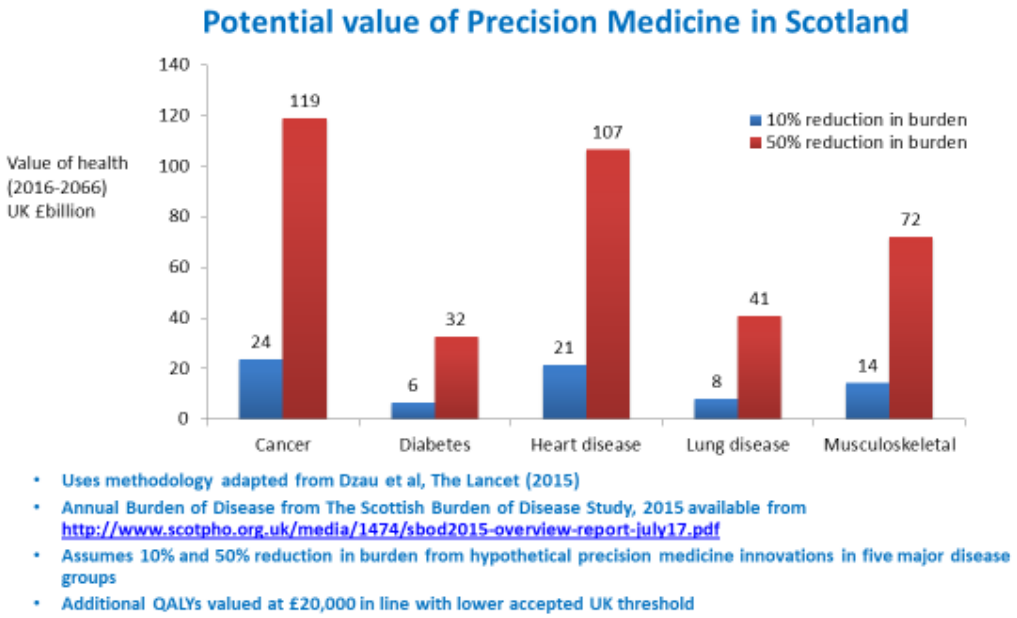
- More integration and exploitation of synergies across clinical medicine and data science capabilities, including machine learning and AI
- Better PM promotion to the SME base and inward investors
- Stronger collaboration between key PM assets and centres of excellence
- Investment in targeted PM, bioinformatics and AI for health skills development programmes

World Innovation Summit for Health 2016:

- The SMS-IC will help organizations develop capabilities and assets to create PM solutions that attract commercial investment and have the potential to generate revenue for Scottish partners. This model is intended to accelerate the adoption of genomic services and enable broader academic, industrial and NHS participation across Scotland.

Potential Value of PM in Scotland (2016-2066):

£73bn to £371bn



Potential Game Changers:

- To combine complementary strengths in PM & data science (health data)
- To develop a "living lab" to realise the potential of PM and drive economic growth
- To develop next generation clinical decision support tools or clinical cockpits utilising machine learning and AI

Peter Silvester – International Perspective

A common vision:

- Healthcare that is informed by each person's unique clinical, molecular, and lifestyle information

Current paradigm is unsustainable and unnecessary:

- In Scotland, net cost of dispensing items alone (includes prescription drugs) is growing at around 8x the current rate of GDP.
- The total (net) cost for dispensing items and providing services in 2017/18 was £1.3 billion … an increase of 3.3% compared to 2016/17 and 25.7% over the last 10 years
- As populations continue to age it's increasingly clear that the current rate of healthcare cost increase is simply unsustainable.
- Most available medicines don't work for everyone - 90% top selling blockbuster medicine only work for 30–50% of patients

Challenges require a collaborative ecosystem – Scotland in a position to lead:

- The Digital Medical Records system is mature, well established and robust
- There's a single payer system which means payment and health care economics can be established, managed and tracked centrally
- There are examples of great partnerships between Industry and Academia
- And the healthcare system and population density provides a critical mass of patients and access to medical expertise that means a successful pilot could be scaled to a national level.

Other health systems, countries and organizations are investing heavily:

Country	**Investment $**
Canada	250m to 2021
USA	290m in 2018
Finland	70m to 2023
Israel	60m to 2024
Saudi Arabia	275m in 2018
Estonia	6m in 2018
Korea	53m to 2021
China	9.2bn to 2030

Pharmacogenomics offers an opportunity to create an ecosystem:

- Regulatory bodies e.g.FDA have already included data on labels of >100 commonly prescribed medications to guide efficacy, dose and potential interactions
- Technology matured to the point that scaled, low cost testing is economically viable
- Results are actionable and benefit all key stakeholder groups
- Studies have demonstrated that the potential is a real and can be achieved

Why now? Why Precision Medicine? Why Scotland?

- the critical foundational elements are in place:
    - 'Single Payer' healthcare system
    - Established digital medical records
    - World class facility with scaled patient population
    - Government committed to change
    - World Class life sciences research infrastructure
    - Vibrant Biotech/SME community

- **the time to act is now:**
    - for Scotland to create a leadership position in precision medicine
      to be the first country to implement an effective precision medicine program at scale, and
    - to create a data asset that will fuel medical research for years to come.

The economics are attractive – the benefits for patients are compelling

- Working for a better future for all of us:
    - For Patients & Physicians:

- Patients educated about the risks and benefits of medication choices
- Physicians provided with tools to inform healthcare decisions
- Advice based on combination of lifestyle, medical history, multi-omic testing
- Better outcomes based on personal information

- For the Healthcare System:
  - Reduced cost of unnecessary prescriptions, reduced adverse reactions
  - Reduced repeat visits for diagnosis, secondary treatment options
  - Better patient outcomes

- For Society:
  - Scaled data asset created to fuel further research and clinical trials
- A deeper partnership between healthcare providers, government, researchers and industry

Luke Delahunty **– The opportunity to combine regional strengths in data science and precision medicine**

<u>Scotland has an impressive portfolio of PM assets</u>

- Well-established Scotland-wide ecosystem for Precision Medicine
- Concentration of assets at new £1bn Queen Elizabeth University Hospital campus in Glasgow:
  - Stratified Medicine Scotland Innovation Centre (SMS-IC)
  - Clinical Innovation Zone
  - Imaging Centre of Excellence

- Wide range of clinical, research and commercial assets based in Glasgow, Edinburgh, Aberdeen and Dundee

- Key differentiators for Scotland:
  - World class clinical research
  - High quality digitised patient data and patient samples
  - Single integrated healthcare provider (NHS Scotland) and large cohorts of patients with chronic disease

- SMS-IC projects showcasing Scotland's expertise and demonstrating the applicability of PM in different areas
  - Several large multi-national consortium projects e.g. AZ's Global Genomics Initiative and the International Cancer Genome Consortium

<u>A rapidly expanding life sciences cluster</u>

- >37k jobs across 700 organisations
- c£2bn in annual GVA for Scotland's economy
- Significant recent growth observed across the sector - 45% GVA uplift between 2010-2015 and employment increased by 16%

- high volume of clinical trials taking place compared to other countries
- 8 out of the top 10 global Contract Research Organisations (CROs) located in Scotland
- an emerging PM business base:

World class research capabilities

- 5 of Scotland's HEIs in the world's top 200 in the categories of clinical, preclinical and health, life sciences & computer science
- Quality of research from 4 SMS-IC partner HEIs (Glasgow, Edinburgh, Dundee and Aberdeen) in PM-related subjects is higher than other key HEI groupings in UK

3 main areas of beneficial impact

- Leveraging new global market opportunities across a range of sectors (e.g. life sciences, data analytics and informatics etc.) to create high value jobs and investment :

  Exploiting major advances in gene sequencing, companion diagnostics, and pharmacogenomics

  Global PM market forecast to grow from $43bn in 2016 to $134bn by 2025 (Frost & Sullivan)

- Implementing PM to generate significant savings for the NHS
- Delivering more effective treatments and better prevention of disease to create a healthier, more inclusive, and more productive Scottish workforce

4 main action areas

- Integrating Scotland's complementary regional strengths in data science and PM
  - Encouraging further/deeper collaboration (esp. between Glasgow and Edinburgh)
  -
- Developing the QEUH campus as a 'living lab' to unlock the potential of PM
  - Building a cluster of co-located PM-related businesses in Glasgow
  - Rolling out pharmacogenomics projects and enhancing the innovation ecosystem
  -
- Creating next generation clinical decision support tools or 'clinical cockpits'
  - New data systems/platforms to accelerate innovation and adoption
  -
- Developing SMS-IC as a key gateway to 'Scotland's Ecosystem for PM'
  - Developing PM tools that extend beyond genomics

Long-term success requires a 'whole system' view.

***Andrew Morris* - The opportunity to combine regional strengths in data science and precision medicine**

From the Twelve Features of High Performing Health Systems (Baker et al 2015)

- Enabling Comprehensive Information Infrastructures and whole system intelligence
- Investing in DATA SCIENCE Innovation and Research– to support economic growth, and population improvement

Why Now? Health care is becoming increasingly data intensive

- Internet and cloud provide connectivity to every corner of the globe
- Smartphone: 2 billion users; 80% of adult population by 2020
- Socialome: the digital data harvested for health and wellness
- Quantified Self: Non-invasive biometric sensing, Tricorder wearables. Apple Research Kit
- Exposome: Pervasive environmental sensing will bring new knowledge to public policy decisions about creating a healthier physical environment, and
- $1000 genome (genome, microbiome, transcriptome, lipidome, proteome, metabolome, multiome/panarome) Stem Cell and Genetic Tx (2000 + trials)
- EHR data: exponential growth of phenome from Electronic Health Records
- Predictive Analytics (Machine learning, A1, and Visualisation). Prediction: TenX more new knowledge from research in silico over RCT by 2020
- Persuasive Technologies: Behavioural and motivational sciences
- "4P" Medicine:

    - Predictive - *Customise diagnosis and treatment*
    - Pre-emptive - *Better than curative – earlier diagnosis*
    - Personalised -*Determine risk profiles, predict outcomes*
    - Participatory -*Involve patients*

- 4P made possible by:

    - Genomics
    - Phenotyping
    - Informatics
    - Analytics
    - New social contract

8 Challenges

1. Skills

- Europe needs 346,000 more data scientists by 2020,
- Up to 77% of such jobs remained unfilled
- 160% increase in demand between 2013 and 2020
- London is home to more data scientist jobs than anywhere else in the country, almost 13 X Cambridge; 16 X Manchester
- London 53% of all vacancies, 51% stated a wage in London, advertised a salary of over £50,000.

2. Complex environment
3. The tidal wave of data
4. Digital Maturity of Health Systems and Data
5. it's going to be competitive
6. Data Quality and standardization
7. Harnessing Inter-disciplinarily
8. Trust

HDRUK Vision

- To create a thriving, high-energy UK-wide network of inter-disciplinary research expertise that will

- Disrupt traditional science by enabling new scientific discovery from large multi-dimensional datasets
- Apply cutting-edge technologies to enhance science, innovation and decision making
- Improve healthcare for a population of 65 Million people
- Triple aim:

    - Integration of data science with biomedical and health science expertise to perform ground-breaking research, with an initial focus on data analytics, precision medicine, 21st century clinical trials and modernising public health.
    - To develop novel approaches to research training and mentorship to foster a cadre of health data science researchers, on a substantial scale.
    - Development and delivery of cutting-edge technologies and trusted research platforms that acquire, store, represent, and process large, multi-dimensional research data.

<u>UK Wide Data Services</u>

- *Establish two to five Digital Innovation Hubs providing data across regions of three to five million people.*
- As part of a national approach and building towards full population coverage.
- These should operate in line with the NDG's recommendations on patient data, and include longitudinal data covering primary, secondary and social care to allow evaluation of innovative tools to establish their impact on care pathways and cost within the healthcare system.
- Capability to accelerate and streamline CTA and HRA approvals

<u>Digital Innovation Hubs</u>

- The right data with the right expertise

    - longitudinal, real time, structured, unstructured, standardised, complete, multidimensional, cross-sectional, citizen generated and internationally relevant.

- Ability to dive deep and deliver longitudinal follow-up

- Non-exhaustive examples:

    - Automated tracking and adjudication for **real world clinical trials**
    - Target validation / mechanism insights from **linked clinical / genetic data**
    - Identifying early disease states / disease strata and **validating biomarkers / imaging**
    - Discovering and validating diagnostic and **prognostic markers**
    - Developing and testing bioinformatics and **AI tools**
    - Assessing clinical / biomedical impact and economic value of **new technologies**
    - Development of scalable **real time analytic tools (including AI/ML)** for clinical decision support

<u>Industrial Strategy Challenge Fund</u>

- Turning health data into early diagnostics and precision treatments. Three complementary strands:

    - Genomics - whole genome sequencing and associated informatics infrastructure, £100m

- Digital Innovation Hubs - linking routine NHS data with rich data from R&D programmes, providing analytic tools and informatics support for businesses alongside local access to integrated UK-wide data, £38m
- Digital pathology, radiology/imaging and diagnosis– centres of excellence in digital pathology and radiology/imaging with AI and machine learning and investment in CR&D to advance diagnostic tools for early diagnosis, £72m (£50m for centres, £22m CR&D)

Precision Medicine in Scotland – reflections

- Opportunity to be Globally Competitive
- Genetics/Genomics Science Base Outstanding
- Increasingly competitive space – across UK, internationally and the world of tech
- Fragmentation still our greatest challenge –

  How does Scotland do business?
  Is the consortium model the right one?

- Creating digital phenotypes within NHS, with public trust, essential for success

***Ken Sutherland* – Development of the next generation of clinical decision support tools**

- We all want the best possible healthcare outcomes for ourselves and our loved ones.
- To get better outcomes we need to make better decisions.
- To make better decisions we need to harness more data.
- We need to aggregate data from different sources to make the best possible decisions:
  - Radiology Imaging, Pathology Findings, Genetic Data, Prescription Data, Vital signs etc.

- …but bringing all of that data together is challenging and complex.
- …and the human decision maker will need next generation tools to help them to use this data to make the best choices for their patients.
- Embedded AI is a key component of next generation clinical decision support.
- To be successful we will need to overcome the following obstacles –

  - IT interoperability, existing patterns of work, public/patient trust.

- We can do all of this in Scotland if we put our minds to it.

***Tim Aitman and Andrew Biankin* – Scottish Science Advisory Council report into medical genomics, emerging findings**

The Brief

- Overview of the current Genomic Medicine capabilities in Scotland
- Comparison with developments in Genomic Medicine elsewhere (UK and international)
- Opportunities and benefits from Genomic Medicine for the NHS, research and life sciences sectors in Scotland
- Where investment is needed to realise this potential

Draft Recommendations

1. **Leadership:** SG to establish a Leadership Group to drive forward policy, challenge barriers and ensure Scotland's world-leading position.
2. **Clinical Priorities:** NHS Scotland to provide a genomics service with the most appropriate evidence-based tests.
3. **Workforce:** NHS Education Scotland to co-ordinate this development with training and resources.
4. **Digital Health:** SG and NHS Scotland to enable data analysis and integrated health management through a high performing digital infrastructure.
5. **Research & Innovation:** SG to work with others to support genomic research and enable growth.
6. **Industry:** SG to work with enterprise agencies to enable implementation of Genomic Medicine as an integral part of Precision Medicine.

Scottish Genomes Partnership

- Universities of Edinburgh, Glasgow, Aberdeen and Dundee; NHS GG&C, Grampian, Tayside and Lothian
- £15M investment by Edinburgh and Glasgow Universities - Illumina HiSeq X Ten platform
- £6M award from Scottish Government and MRC
- Scotland amongst first 20 worldwide to install HiSeq X
- Edinburgh Genomics Sequencing Facility
- 9,958 whole genomes sequenced (June 2018)
- Link to Genomics England

Exceptional QC for whole Genome Sequencing at Edinburgh Genomics (Clinical)

- Genomics England: "No queries on either sample swaps or data entry errors. This is a major achievement when entering such complex information on large numbers of participants."
- UK NEQAS: "The Scottish system is a high quality, good approach."
- ISO 17025: Final audit passed August 2018.

It's not rare to have a rare disease

- A rare disease is defined as one that affects less than 5 in 10,000 of the general population.
- 7% of the population (1 in 17) will be affected by a rare disease at some point in their lives.
- 80% of rare diseases have a genetic component.
- 75% of rare diseases affect children.
- Often rare diseases are chronic and life-threatening.
- They include rare cancers such as childhood cancers and some other well-known conditions such as cystic fibrosis and Huntington's disease

Public Engagement and Confidence

- Awareness Raising
  - Information provision and public education

- Consultation
  - Insight into public views and opinions

- Empowerment
  - Working with the public enabling them to play a part in decision making

SGP - Precision Oncology

- Pancreatic cancer approaching second leading cause of cancer death in Western countries
- Precision – Panc is a UK-wide, globally significant study which has identified for the first time four sub-types of pancreatic cancer.
- With £10m CRUK funding, Precision Panc is using real world precision medicine to identify the right trial for the patient – over 600 patients being recruited
- Glasgow Precision Oncology Laboratory (GPOL) can deliver all genome sequencing and analysis to inform treatment/trial decisions
- Scotland leads the International Cancer Genome Consortium (ICGC), headquartered in Glasgow
  - Comprehensive mapping of cancer genomes
  - Accelerating Research in Genomic Oncology (ICGC-ARGO) – providing multi-omic data for cancer clinical trials

***Fiona Murphy* – NHS Perspective**

Background to NSS Specialist Healthcare Commissioning

- Diagnosis & Screening: advanced, early, accurate
- Networking across geographical professional boundaries
- Specialist services – surgery, medicines
- Once for Scotland:

  - equity, economy of scale, resilience, quality, standardisation - manages variation,
  - reduces financial risk

  - experience and knowledge of planning specialist tertiary services, networks and diagnostics in Scotland

  - national focus across territorial Boards - reduced Variation

  - specialist healthcare planning, healthcare science, IT, public health, information, procurement skills

  - work in partnership with territorial Boards, to help them deliver their goals

- Scottish Genetics Consortium (Glasgow, Lothian, Tayside, Grampian hubs). Cost per hub rising (total: £10m in 2009/10 to £16m+ in 2017-18)
- Working with Scottish Genomes Partnership and GEL/100,000 genomes project

Challenges

- Poor relative health + inequalities = need for Scotland's health to improve
- Ageing population + complex care needs = increasing served demand
- Increasing demand + tight budgets = financial pressure

National Commissioning in NHS Scotland

- Key Questions:

  - Does the service / intervention / network proposal work?
  - Does it add value to society?
  - Is it a reasonable cost to the public?
  - Is it the best way of delivering the service?

- New Designations

  - Agreed and funded by ALL Territorial Boards
  - Annual prioritisation of new proposals

Scottish Genomes Partnership

- Progress in answering these questions for WGS:

  – Effective - evidence base developing

  – Valuable:
    Patient benefit and family impact clear
    Health Economic evaluation (UoA) - cost-efficiency of WGS vs. other methods of genome-based and single-gene testing.

  – Affordable
    Not on current budgets
    Step strategy meantime

  – Feasible
    Development of protocols for delivering WGS in NHS Scotland
    Understanding IT and Data storage requirements for NHSS genomic data.
    Developing workforce and education plan – specialist & non-specialist

Scottish Genetics Consortium

- Testing Strategy

  - Develop NGS (Next Generation Sequencing) panels
  - Develop targeted sequencing using the clinical exome
  - Introduce trio-based whole exome sequencing for diagnosis of developmental delay in Scotland
  - Evaluate use of whole genome sequencing with federated analysis in patient care through collaboration with the 100,000 genomes project
  - Implement NGS techniques for molecular pathology of acquired disease and primarily the areas of cancer diagnosis, predictive and prognostic testing

NHS Scotland Readiness Assessment

Strengths

How we are organised – already "Once for Scotland" for genetic tests
Scottish expertise in Genetics and Data

Partnerships - consortium, clinical and academic, potential with other nations, academic and industry

Weaknesses

Lack of collective overall strategy
Evidence and cost effectiveness for genomes
Dealing with data - storage and sharing
Sustainable workforce -succession planning & flexible training solutions
Engage users, wider users (e.g. GP's)
Patient information, education and consent

Opportunities

Benefits of a steps wise approach – building on current knowledge & experience
Collaborative working with NHSE for the evaluation of testing
Collaborative working with academia and industry colleagues to aid streamlining of informed research into clinical practice.

Funding

Need for Investment to bring genomics into NHS service – not just for innovation but sustainability and developments to improve current service provision e.g. Move to NGS and mainstreaming services

<u>Why enhance Genomic Medicine?</u>

- **Rare Disease -** Diagnose disease, Diagnose rapidly
- **Cancer -** Choose best drug, avoid unnecessary treatment (& side effects) / Stream patients to appropriate Clinical Trials
- **Precision Medicine** - Genetic markers for right drug for other diseases: cardiology, diabetes etc / Predict adverse reactions
- **Prevention (potentially) -** Stratification/extension/development of targeted population screening, early detection of risk
- **Research -** new diseases, new genes, new drugs, lifestyle
- **Economy** - life sciences – bioinformatics, diagnostics, technology, drugs, enhance and exploit Scottish expertise in Big Data
- **Financial** – enhance use of prescribing budget, diagnostics, patient pathways, reduce waste

<u>Why now?</u>

- Maintain momentum
- Retain highly qualified staff
- Build on world leading academic skills
- Enhance Relationships
- Provide equity of access for patients
- Ensure independent access to high tech
- Build on capabilities in key strengths

<u>How?</u>

- **Engage** with NHS (Clinicians, planning, management – personalised medicine will be disruptive)
- **Invest** in mainstream (NHS) test development
- Develop comprehensive **Informatics/Digital** plan
- Whole system approach to **education** – clinicians, patients
- Consider **redesign** of existing services e.g. cancer pathways

- **Collaborate** with UK – especially on data sharing, patient information, learning re new findings, consent, family sharing, insurance moratorium, data and informatics
- Continue **investment** in research

Future actions

- Evidence
- IT systems/data
- Skills
- Engagement

Dave Tudor – Precision Medicine within the Life Science Strategy for Scotland (no slides)

- Echo all previous presentations which fit well with the Life Science Strategy for Scotland and its ambition to double the turnover of the sector to £8bn by 2025

- The sector employs 37,000 people across 700 organisations

- Company turnover in excess of £4.2bn; GVA of around £2bn

- Life Sciences encompasses animal bioscience, agritech, aquaculture, industrial biotechnology and health/medicals technology/pharmaceuticals – health sector is a key grow area

- Strategy being implemented through an Industry Leadership Group (industry, NHS, academia and Government) and focused around 4 themes: Sustainable Production; Internationalisation, Business Environment; and Innovation and Commercialisation – latter is particularly relevant to health sector and to Precision Medicine

- NHS/academic/industry collaboration therefore vital to success of Life Science Strategy for Scotland

- Solid foundations: eg NHS Research Scotland (NRS); SMS-IC; investment in QEUH; "once for Scotland approach" – agree with all plenary speakers that we need to build on those to develop/implement Precision Medicine further, on a One Scotland basis, to deliver significant and transformational opportunities for both health gain and economic growth

- Opportunities are there, not least through UK Industrial Strategy funding – need to seize them now

ANNEX D
PM SUMMIT - ROUND TABLE DISCUSSION: POINTS RAISED

1) Opportunities for healthcare innovation and economic growth for Scotland: barriers and solutions

Data

- Need for a framework which brings together capacity to work at scale; workforce data, healthcare data, pan Scotland (rather than building separate data sources for discrete problems).
- Clinical data quality, completeness, standardisation of format, interoperability (defragmentation of data systems) and availability all need to be improved and are crucial to support research and innovation and real-world-real-time evaluation.
- Data collection – must be uniform and useable.
- Clear routes/places to access and analyse the data.
- Routes for feedback, update, correction of data.
- Improve phenotype data:
    - Need to go back and learn.
    - Develop safe havens.
    - Improve ability to work inside safe haven for AstraZeneca.
- Data collection and sharing across agencies: siloes; R&D or clinical data? quality of input - lack of time and resource to do this (clinical).
- Deficit in clear policy around the rules of engagement for industry to use NHS data that take into account:
    - the nature of the engagement and existing regulatory frameworks (e.g. pharma company using data for drug or diagnostics developments and operate under clear regulatory framework by MHRA versus IT company (e.g. Google) using data to support service provision but who regulates this?),
    - arrangements for appropriate financial return or other benefits for the NHS.

- Need to develop clear and firm (non-negotiable) policy on the rules of engagement for industry's use of data and have simplified well understood routes of access and point(s) of contact to make use of NHS data in a well-managed, controlled manner, ensuring public benefit is realised. Policy development needs to be founded on dialogue, clear understanding and taking full account of patient and public expectations, and a robust consent model. Patient voices are a powerful way to inform wider public opinion. Precision Medicine is not well-understood publicly; need to bring this concept to life for patients and public.
- Attention to enabling access to patient level data – enabling intrinsic structure for accessing data electronically (not on paper)
- National platforms – cloud, systems!
- National standards!! – Sovereign standards already.
- Language interpretation software – digital health strategy very important.
- A unified data front door for business building on safe havens (CRUK).
- Need to build platform for inter-operability (make Scotland more competitive).
- Need more joined-up systems in NHS to contribute data.

Workforce

- Need to build the workforce by creating teams with the right skill sets to grow and retain scientists and researchers in Scotland
- 9+1 Contract:

- Inhibits medics to do research – lack of clinical time for research – consultants and juniors (not specific to precision medicine).

- Capacity of NHS to engage and support a triple helix approach and to develop, evaluate and adopt innovation is too limited, particularly given the need to balance competing demands. Additionally, implementation of some innovations may need double running of existing and innovation driven approaches/products. Support and capacity to do this is also limited:

    - Data scientists supply.
    - Educating wider NHS re precision medicine genomics and map out full spectrum of skills regulations.

- Joint appointments.
- Train own staff and develop.
- Tap into intrinsic motivations.
- Facilitate what is good/rewarding about public sector/NHS.
- More capability for NHS/academic innovation. (NIHR sorting out devolved spend re innovations separating acute healthcare vs innovation).
- SMEs need to understand clinician needs (CRO/NRS Fellowship Programme – good start). Health Board helped to backfill but need to be more drastic solution even with modest innovation investment.
- Training - Right people, right things; Clinical data scientists; Career paths …?
- Workforce key - need to grow the entrepreneurs skill set.
- Training - Data science PHDs? Implementation science?

Realising Precision Medicine

- Improve governance between NHS boards and support better collaboration for a collective effort.
- Need to develop innovation infrastructure to support new drug development companies and serial entrepreneurs (attracting people to Scotland).
- Clear shop window and structures for industry to engage.
- One front door that makes right connections/pathways.
- Map Scotland's ecosystem.
- Clear brand (eg Health Innovation Manchester and Cambridge).
- Don't forget wider worldwide collaboration skills capability/capacity retentions.
- Living laboratory:

    - Set of pharmacogenetic tests before treatment. Low cost prevention – save on adverse reactions.
    - Full cost benefits/role of health economists.
    - Embed within health board.

- Barrier politics/process in NHS:

    - Delay in process.
    - Bureaucracy (red tape!).
    - System saves money.
    - Needs more dynamic/increase slickness of operation.
    - Responsive clinical governance.
    - Pan-Scotland. Once for Scotland.
    - Same pan-Scotland permission arrangements.

- How to upgrade infrastructure/system roadmap – feasibility driven not academics only.
- Need culture change: co-created vision led by SG.
- Relationships/roles/responsibilities

    - Core platform to provide connectivity.
    - Balance specific/general.
    - Exemplar projects of interest to industry.
    - Better links 3rd sector.
    - Idea where we want to be world leader but applicable more deliver against strengths and then grow generally.
    - Business case to de-toxify risks.
    - Focus on chronic diseases and common cancers.
    - 3rd sector, funding councils, SG, UKG industry, philanthropy, Wellcome Trust etc, universities.

- PM wider than genomics other omics which develop over time. Implications for lab facilities and expertise to deliver precision medicine tools dynamic measurement.
- Route to Market:

    - NHS 14 Boards.
    - No way of rolling out innovation especially for new SMEs who is not known.
    - NHS can procure but clinicians decide
    - NHSScotland – end user

- How to build cluster and accelerate precision medicine adoption, new innovations and new businesses.
- How to facilitate private sector.
- Challenge of servicing divergent customer needs simultaneously - e.g. NHS / Pharma / Diagnostics Companies
- England/Wales – innovation partners.
- Mapping of precision medicine innovation – who is innovating? – Academic NHS/Scotland SME/Inward investor.
- Need better incentives for collaboration/governance – who is responsible for healthcare innovation and how structured.
- Precision medicine ecosystem for Scottish ideas only?
- Other LS hubs – critical mass of VCs and global players – Scotland is place to come.
- Issue of dealing with overlapping assets eg a bucket trial involving multiple pharma companies all trialling same-class drugs was cited as being difficult to configure to address customer needs equitably.
- More regional planning to pool innovation resource
- Siloed budgets and thinking.

Patient/public involvement

- The absolute need for a focus on customer needs and drivers (customers including the NHS, Industry and public sector funders).
- Patient involvement – must adopt nationally – off the shelf do not reinvent.
- SHARE £250k volunteers for precision medicine?
- Need to be able to use results and prove treatments.
- Genotype dementia treatments will follow.
- Patient education – links to realistic (goes both ways) medicines and support for understanding.
- Withdraw people from screening/medication – cost.
- Building confidence amongst public need strategic vision for implementing precision medicine building momentum through quick wins.
- Need to open up innovation – however this has potential for public alarm due to involvement of industry.
- National consent a major issue – need public engagement on this issue.
- National conversation re ethical impacts, public engagement eg 'drug won't work for you but no alternatives'.

Exemplar projects

- Previous initiatives were felt to have been orientated towards discrete investments without an emphasis on connectivity and integration. Use case model to address the above concerns:

    - This might involve a vertically integrated value-chain based model. The would be exemplified by a small number of high value / impact exemplar projects

    - Two current examples are the Precision Panc and Lung Matrix trials
    - The exemplar initiatives would not necessarily be defined by diseases– for example the development of a pharmacogenomics-based precision medicine approach could cut across multiple clinical areas. However if the exemplars were to be disease based then both cancer and rare conditions were thought to offer tractable opportunities

- The above model has the example of focussing on a manageable number of tractable issues – thereby avoiding the problem of attempting to "boil the ocean" that a more diffuse approach might encounter

- Acknowledgement that the vertically integrated model could be considered a "silo" approach – however it was felt that if the use cases were of sufficient scale that the outputs would be transferrable

- The identification and selection of use case exemplars would be through a competitive bid process based on an impact-bases business case evaluation – SG would have a central co-ordinating role in this process

2) Integration of precision medicine into NHS Service – collaborative working between health boards, academia and industry

Power of exemplars

- Need to innovate by doing – look for test cases and build on these. SMS-IC potential to develop exemplars. Possibility of using existing data available (e.g. Guthrie test).
- Role of SMS-IC as shop front
- Test examples will help to explore and respond to challenges (collaboration legal issues, consent and public engagement)
- Prescription data and pharma testing maybe a useful example.

- Strong example – SMS-IC build upon.
    - Expand current exemplars eg MS bringing data together to inform patients.
    - Custom data entry for MS!
    - Specified dataset put into EHR- clinics across country + patient reported outcome measures - MS data, repository linked to imaging etc.
    - NASH, patient management COPD,
    - Getting information to clinician.
    - One source.
    - Timing – pre-emptive?
    - Must get precision medicine information back to clinician and use it beneficially – tools/processes to do that.
    - Scotland-wide consent form.
    - Must join up players better – NHS, academia, industry.
- Economic growth on the back of clinical excellence.

Capacity

- Capacity of NHS to engage and support a triple helix approach and to develop, evaluate and adopt innovation is too limited, particularly given the need to balance competing demands. Additionally, implementation of some innovations may need double running of existing and innovation driven approaches/products. Support and capacity to do this is also limited.
- Need to ensure sufficient and flexible clinical time is dedicated to support a triple helix approach with efficient infrastructure to support development, evaluation and adoption of innovation.

AHSNs

- National or regional 'front doors' focussed around a national or 2-3 well coordinated regional Academic Health Science Networks can facilitate greater coordination, act as a magnet for inward

investment, and as a way to make that investment stick within Scotland rather than IP being exported for development elsewhere. Centres of excellence may be helpful.
- AHSN(s) need to be sufficiently well and stably funded, and have agility and decision making capability e.g. on what areas, projects or companies to target.

IP

- Need attention to IP and to develop guidance
- IP sharing and spin outs from NHS.
- Clarity re IP benefits to NHS.
- How to ensure IP for NHS to encourage what is pay-back period?
- IP issues with biomarkers preventing commercial success.

3) Additional/new investment needs and potential sources

Infrastructure

- Need to build the funding infrastructure to enable capital investment at scale.
- Rather than being reactive to ideas, need to create a strategic approach which provides context and help ideas grow.
- Need to support engagement between industry and the NHS and funding sectors which may have an interest (Scottish Enterprise, national investment bank). Demonstrate test cases in the NHS will help to attract attention of investors.
- Solution facility incubation to prove cost effectiveness – need to bundle with comprehensive diagnostics.
- Seed fund to enable industry/academic collaboration.
- Greater flexibility between funding to ensure innovative ideas get off time ground (understand what they provide).
- Financial reward for HEIs.
- Coordinated programme of activity building on excellence (higher risk funding).
- Inward investment "sell working in Scotland".
- Need further investments to ensure data integration across primary/secondary care bringing together data systems.
- Need to be more attractive for external investments:

    - One source of info, timing of info availability
    - Suggestion of pre-emptive genomics
    - Scotland-wide consent
    - Must join up players better: events like this help

- SG funding for whole genome and keep testing going.
- Rare disease genetic testing.
- Supportive arrangements for collaborative working need to be flexible to take into account the company base i.e. the support needs for collaborations with big (multi-national) companies versus SMEs.
- Collaborative working across Scotland needs to be incentivised (approaches being explored in British Columbia may be informative such as targeted funding contingent on a level of partnership working e.g. threshold number of health boards, working with a number of Universities and industry).
- Scotland too risk averse? How link those with ideas to those with money?

Define the business case

- How to define precision medicine – what does a business case look like? Need to revisit definition in current funding streams to reflect life sciences. Potential in focussing on data investment?
- NHS funding inflexible – changeable, eg -
    - Pre-emptive data collection – investment!
    - SHARE bloods – genotype/phenotype – outcomes data.
    - SMS-IC – living lab pilot in Scotland.
    - Infra in-centre – external funding.

- Continued support for SMS-IC etc.
- Selling and telling Scotland's stay in this space: priorities, align to Scottish health challenges
- Need to be clear what money is needed for a business case.
- Lead to better business cases and encourage private sector investment.
- SG/funding encourages other sources of funding public sector – base funding to establish leverage.
- Any investment must demonstrate how NHS will benefit financially and improve service for patients. This will help to build public confidence and trust.

4) Other

Regulatory Challenges re product validation

- Waiting too long for everything in place.
- Produce roadmap for Scottish products and services.
- Focused priorities for early deliverables.
- Coordinate precision medicine research demonstrating health outcomes for these innovations.
- Help with public/business engagement.

Scotland's Precision Medicine Summit: 10 September 2018

First Minister's Opening Speech

Thank you, Anna and David. I'm grateful to both of you for chairing this Summit and for all the work you've done to organise today's programme.

I also want to thank all of you – for contributing your time and your expertise to what I think will be a hugely important discussion.

For nearly 200 years, Scotland has been at forefront of healthcare innovation.

Scottish discoveries and inventions – like penicillin, the saline drip, and the hypodermic syringe – were key to the development of modern medicine.

Early Scottish healthcare schemes – such as the Highland and Island Medical Service and the Clyde Basin Scheme – not only broke new ground, but provided the model for the NHS.

And the creation of the NHS in turn enabled and encouraged a new wave of medical advances in Scotland – like the first beta blocker, the first clinical MRI service; the first practical use of ultrasound.

That outstanding record of achievement is one of the things we are celebrating throughout 2018 – as we mark 70 years of the NHS. However, it's also appropriate – in this anniversary year – for us to look to the future of healthcare in Scotland.

That's what this Summit does.

As you know, one of the most important developments of recent years has been the emergence of precision medicine. It has the potential to transform the way we treat and prevent disease. By tailoring healthcare to fit an individual's genetics and lifestyle, **precision medicine** promises to deliver major benefits – in terms of earlier diagnosis, more effective treatment and better targeting of resources

Scotland has all of the potential to be a world leader in developing precision medicine. I saw that back in April when I visited Hong Kong and China. I spoke to quite a lot of companies there about precision medicine. And they showed real interest in what Anna likes to call the Triple Helix – the three key strengths which Scotland has to offer.

First, there's the quality of our academic research. Per head of population, Scotland has more world class universities than any country in the world, apart from Luxembourg. We lead every other part of the UK in attracting research and development projects. And our universities boast particular specialisms in the areas most relevant to precision medicine – such as genomics, data and informatics, and clinical medicine.

Second, Scotland is more successful than any other part of the UK in setting up businesses to commercialise our research. That's one of the reason why we have such a thriving life sciences sector. Scotland is home to more than 700 life sciences companies - and over 200 of them are involved in precision medicine.

Third, our single unified health service – NHS Scotland – maintains healthcare data of unparalleled quality. For example, through the Community Health Index we have a comprehensive source of patient, clinical and demographic information – covering a population of over 5 million people.

As precision medicine is data-driven – and depends on information about patient genetics, environment, and lifestyle – that's a huge asset. And – together with our academic and industrial strengths – it's one on which we're determined to capitalise.

That's why the Scottish Government has taken a number of major steps to support the development of precision medicine in this country.

Since 2013, we've provided £8 million for the creation of the Stratified Medicine Scotland Innovation Centre. It's undertaking major research projects – on diabetes, oncology, irritable bowel disease, rheumatoid arthritis, MS and pancreatic cancer.

In addition, we've also provided funding for the Imaging Centre of Excellence at the Queen Elizabeth University Hospital. It's the first clinical facility in the UK to have a 7 Tesla MRI scanner. And it has already established itself as global hub for precision medicine research.

I visited the Imaging Centre in January. And while I was there, I spoke to some of the academics and entrepreneurs who have come from across the world to use the facility – and to invest in this country. It's a good example of how our support is already helping Scotland to attract the more talent, expertise and investment.

We now want to build on those foundations. One way in which we aim to do that is by developing Scotland's capabilities in genomics. After all, using data on an individual's genome – their complete set of genes or genetic material – is a key part of our commitment to precision medicine.

Scotland's reputation in this field is already strong. The Scottish Genomes Partnership brings together expertise and resources from the universities of Aberdeen, Dundee, Edinburgh and Glasgow - and our NHS. It is undertaking vital research into rare diseases and cancer. And it collaborates with Genomics England on the 100,000 Genomes Project. That involves the sequencing of 100,000 patient genomes, in order to improve the way we diagnose and treat certain diseases.

The Scottish Government has provided significant funding for the Scottish Genomes Partnership. Our priority now is to enhance Scotland's current capabilities. That's why – when we published our Programme for Government last week – we included a commitment to enhance our support for genomics.

Today I can announce that commitment will be backed by an investment of £4.2 million over the next three years.

That money will be targeted in a range of different ways. For example, it will be used to extend Scotland's participation in the 100,000 Genomes Programme, and our collaboration with Genomics England. That will help Scotland to retain the benefits of the investment we've already made. And it will ensure that Scottish patients – by having their genomes sequenced - can continue to receive more accurate and precise diagnoses.

We'll also invest in the creation of training schemes and new resources for staff - within our clinical and laboratory services, and our NHS.

Finally, we will ensure Scotland has a central facility for storing genomic data. At the moment, our four Genomic Centres and our NHS lack the capacity to effectively share data. Investing in a secure and efficient digital platform will change that. As a result, all experts in Scotland will have access to the same scale and quality of data.

Overall, our investment aims to ensure that new insights and breakthroughs in precision medicine are even more likely to come from Scotland in the future, than they have been in the past.

That will be good for patients, as we come up with better treatments. And it will of course have economic benefits, if those treatments have application around the world.

Our investment in genomics over the next few years will therefore make a real difference. But we recognise that developing Scotland's capabilities in precision medicine is a long term endeavour. And we know it will require coordinated action, across a wide range of areas.

The BEIS Audit of Precision Medicine in Scotland – which is being led by the University of Glasgow – will be a huge asset in informing our approach.

But we also want to hear directly from all of you – leaders in your different fields, and your different industries. Your expertise, experience and hard work has already helped Scotland to become a prospective world leader in precision medicine. Today is an opportunity to discuss how we can build on that potential – together – in the years and decades ahead.

So thank you all again for being here. I hope you find today's Summit valuable. And I look forward to hearing the outcomes of your discussions.