Testing Process and Products – Supply Chain

Step	Test	Activity	Products	Comment (Amber = Oversight Group work)
1	Nose and Throat swab into viral transport medium	Take Sample	Test Swab Kits. These are being sourced from across UK and internationally. We are also working with SMAS to scope the potential for manufacturing in Scotland	2.4m swab kits ordered with regular deliveries scheduled over the next few months. Back-up suppliers being identified to ensure resilience of supply - Extra stock not required. **Inactivation media** (used as an alternative to above as it simplifies downstream testing procedures) – trial production by E&O Labs (Cumbernauld). Final product needs to be validated in terms of proving its ability to inactivate the media. Some enquiries underway. Action: If ILG members could suggest facilities capable of testing batches then this would be helpful **Dry swabs** – will be required for use with the inactivation media above. Enquiries underway to identify suppliers, and workstream encouraged to develop a 'make' strategy for dry swabs in Scotland to ensure resilience of supply chain. Plastics manufacturer required that is ISO-accredited for medical supplies. SE/SMAS working on this. Action- Comments or other input welcomed from ILG members
2 -6	Catalogue the receiving of sample, Test for leaks within the inner bag - visual test, Physically label sample; Book sample into lab management system	Transport Sample; Receive Sample, Unbag and label Book in Sample	Put sample into packaging conforming to UN3373 From this point much of the activity below can use kits made specifically to suit the available analysers. We are therefore sourcing purification and viral testing kits (see below):	No further support required.

7	Add lysis buffer to tube kill the virus and release the RNA and DNA into the free fluid environment	Pre-Process Sample -lysis	Lysis solution and consumable equipment to do this Seeking to make or buy suitable lysis solution.	Large scale supply required for use in testing labs. E&O Labs making batches of lysis (for use in the inactivation media) – possibility of them scaling up to meet wider demand. SE also working with 3 other Scottish manufacturers (Johnson Mathey, Calachem, Ingenza) to scope out possible manufacture.
8	Isolation/purification of genetic material of the virus, and anything else that has genetic material	Extract RNA	Multiple different proprietary systems: One Example: Viral RNA extraction: VWR Omega Biotek MAG-BIND® VIRAL DNA/RNA (12 x 96) KIT (or equivalent such as ThermoFisher MagMax extraction kit), ThermoFisher Kingfisher Flex Plasticware: 96-well elution plates (97002540); 96-well deep well plates (95040450); 96-well tip combs (97002540); Performed on a ThermoFisher Kingfisher flex robot.	**Ethanol** – required for washing steps in lab testing process. High demand of lab grade ethanol, although some availability identified through Sigma Aldrich. Alternative bulk supplier identified in Scotland (distillery) – grade meets lab standard, however issue with dealing with relatively small amounts (distillery delivers tanker loads; lab requirements are 2.5L bottles) so bottling issues will be progressed if an immediate supply (Sigma Aldrich) is not forthcoming. Support being provided by Hand Sanitiser workstream, so confidence this can be resolved if required. <u>No current ask of ILG members.</u> Fisher supporting 28k tests a week. Optical Adhesive Covers - Catalogue No. 4481190 Optical Adhesive Covers - Catalogue No. 4311971 98W Fast Plate GPLE, Catalogue No. 4481190 RealStar® SARS-CoV-2 RT PCR Kit 1.0 CE
9	"Mastermix" addition. This starts the process for starting the polymerase chain reaction, to stick to the virus and increase volume to enable detection	Add Reagents	Multiple different proprietary systems: One Example: "MasterMix" Solution and consumable equipment to do this - real-time RT-PCR consumables: Thermofisher TaqPath Covid19 CE-IVD testing kits (PCR primers and probes/mastermix from other sources also a backup option)	No Current ask of ILG members.

10	Very small test tubes on in an injection moulded plate	Transfer to Batch Plate	Multiple different proprietary systems: One Example: ThermoFisher MicroAmp Optical 96-well Reaction Plate with Barcode 0.1 mL; (4316813) and seals optical (4311971)	Consistent stock –
11	Temperature cycle with a detection molecule, a fluorescent probe, that produces a signal if viral nucleic acid detected.	Amplify	Multiple different proprietary systems: One Example: Performed on ABI 7500 equipment (installed)	No current ask of ILG members.
12	The fluorescent signal is detected by the machine generating a trace that is interpreted by the test operator	Detect / Interpretation	Multiple different proprietary systems	No current ask of ILG members.
13	Waste treated as clinical waste	Discard Sample	Samples stored for 1 week before disposable. (large sealable plastic containers needed)	No current ask of ILG members.
14	Result is verified and sent to the correct location for communication to patient	Result		No current ask of ILG members.
Other	Antibody			• Antibody test validation is being undertaken in UK and in Scotland. Processes are similar. Offers are sent to a central mailbox and are triaged by NHS clinical leads. • There are a few different kinds of Antibody test in the validation process. In Scotland, lateral flow tests are evaluated by NHS Lothian whilst ELISA and large analyser tests are sent to Dundee. • As they move through the process, the NHSS programme office keep companies updated on progress • Once a test has been validated, the company will be informed and procurement processes will start. There are currently 2 Scottish companies in that process. Action- ILG support and advice through members such as ODx would be valuable.

SUBJECT: Digital Health and Care Transformation
MEETING DATE: 15th July 2020
AUTHOR: Scottish Enterprise Health and Wellbeing Team / ILG medtech group

~~For Information~~	~~Members are asked to note the contents of the paper~~
~~For Discussion~~	~~Members are asked to decide on recommendations~~
For Approval	**Members are asked to agree to recommendations in the paper**

Summary

Digital health and care transformation, whilst being a priority for the ILG's medtech group, has also implications beyond medtech in pharma and other areas. It is therefore proposed that an initial scoping subgroup is set up, within the ILG, to prioritise the areas of focus.

It is anticipated that the work of the scoping subgroup will lead to proposing a wider workgroup that includes relevant stakeholders and experts[1]. This workgroup will aim to develop an action plan focusing activities of industry, NHS and digital health and care stakeholders to identify and communicate needs, develop or provide solutions, support clinical testing, and drive adoption and global commercialisation of these solutions. Through this action plan, the workgroup will aim to inform and influence stakeholders and decision makers to make Scotland a world leader in innovative digital health and care solutions improving the delivery of health and care for its citizens and commercialising these solutions globally.

It is suggested that the scoping subgroup should concentrate on specific areas including the six listed below. These include areas where Scotland has distinctive competences:

- Health and care data. Scotland needs to exploit the competitive advantage conferred by its Community Healthcare Index (CHI) number and associated health and care data to its full potential, ensuring data quality, completeness, interoperability and accessibility. Legal, ethical and commercials frameworks for access need to be defined.
- Development of AI for diagnosis and other applications. Scotland should leverage significant local industry expertise and existing industry academia collaborations to generate clinically validated solutions.
- Development of Internet of Things (IoT) solutions to support remote and home-based health and care and enable more efficient use of NHS assets, building on existing networks already deployed in Scotland.

and business environment areas where growth can be accelerated through:

- Facilitating mechanisms to test and validate new technologies in clinical or care settings and developing mechanisms to increase adoption and deployment of such technologies when proved beneficial.
- Communicating the needs of the health and care sector and requirements of operating in such sector to the digital industry. The Scottish digital industry base has capabilities, expertise and solutions applicable to satisfy needs of the health and care sector. However, too often digital companies are unaware of both these needs and associated regulatory requirements.
- Leverage resources to develop trade by ensuring global commercialisation of Scottish digital health and care solutions and build on Scotland's reputation and testing and validation capabilities in the field to attract trade and inward investment. This will be conducted in close collaboration with the ILG's internationalisation group.

[1] **[REDACTED]**

Actions

The medtech group seeks approval from the ILG to proceed with setting up the above-described scoping subgroup.

Recommendations

Approve the recommendation to set up the initial scoping subgroup.

The body of the paper below explains what is meant by Digital Health Transformation and provides a more detailed overview of the opportunities, challenges and Scottish strengths in this area.

1. What is meant by Digital Health and Care Transformation (DHT)

This topic encompasses all the changes related to adoption and deployment of digital technologies to improve health and care. This also includes such digital technologies used in upstream R&D and manufacturing activities to improve health and care.

Health and care improvement is taken in its wider sense of the prevention, monitoring, diagnosis, treatment, recovery, or cure of disease, illness, injury, and other physical and mental impairments in people.

Digital technologies are electronic tools, systems, devices and resources that generate (*e.g.* sensors), store (*e.g.* databases), transmit (*e.g.* 5G networks) or process data (*e.g.* hardware such as microprocessors and software such as artificial intelligence programs).

2. Opportunities

Like in most developed economies around the world, the Scottish health and care system's sustainability is challenged[2]. Ageing population and lifestyle have led to an explosion of patients with chronic diseases while diagnoses and treatments have become more advanced and expensive.

Responding to this challenge will require paradigm changes and innovations that will afford increased efficiency, better patient outcome and opportunities for significant economic development. Examples of specific improvement to be addressed include:

- Prevention;
- Diagnosis efficiency and accuracy (including omics analyses, radiology and pathology);
- Treatment approaches leveraging data and precision medicine;
- Physician patient interaction (efficiency and quality);
- Patient management;
- Management and analysis of patient data;
- Value-based healthcare technology assessment process;
- Management of patient conditions (including monitoring and self-management, prescription ordering and compliance management);
- Research and discovery (including omics),
- Manufacturing and distribution,
- Ageing population often supported at home not in hospital.

These challenges are also opportunities and the digital healthcare market is growing significantly supported by underlying technological developments. Before the Covid-19 crisis Valuates estimated the global digital health market size at USD 103.1 billion and projected a CAGR of 24.6% leading to USD 385.8 Billion by 2025[3]. Technological developments in hardware, software and biological sciences

[2] NHS in Scotland 2019, Audit Scotland, https://www.audit-scotland.gov.uk/uploads/docs/report/2019/nr_191024_nhs_overview.pdf
[3] https://reports.valuates.com/market-reports/QYRE-Othe-0A163/digital-health-market

offer some of the tools to provide solutions to the above challenges. There are numerous reports setting out how digital technologies can contribute to health, and there are already 800 million global users of digital health services such as symptom checkers, mental health services, digital therapeutics, telehealth and fitness trackers[4]. The Topol Review[5], assessing how to enable NHS staff to make the most of innovative technologies, identifies three key areas of digital opportunity:

- Genomics (diagnosis of genetic diseases, gene therapies);
- Digital medicine (how people interact with healthcare – telemedicine, apps, prescription ordering, remote monitoring, augmented reality for training);
- Artificial intelligence (image interpretation for radiology/pathology, speech recognition, improved data insights to allow better management/self-management of conditions).

As importantly, the Covid-19 crisis has highlighted inefficiencies leading to a renewed emphasis on digital solutions and demonstrated a step change in rapid adoption of technologies and new ways of working. The fact that healthcare services have demonstrated they can adopt new ways of working quickly, coupled with increased awareness/demand for better solutions, will likely result in a shift in willingness to coordinate and adopt solutions in the future. It may also prompt a cultural shift amongst key workers who may be more willing to adopt solutions if there is a benefit to their own wellbeing. There is an opportunity to seize this new dynamic and expand it beyond Covid-19 related solutions to ensure long-needed change happens.

This new dynamic in adoption of novel solutions, is an opportunity to implement mechanisms to utilise Scotland's Community Healthcare Index (CHI) and unique longitudinal data to its full potential. Scotland's Data Scoping Taskforce identified specific opportunities to use data to improve the assessment, introduction, safety and effective use of medicines. Enhancing Scotland's health and care data capabilities would deliver significant improvements in patient care (including improved outcomes and increased safety) and citizen's wellbeing, as well as enhancing Scotland's reputation in health and care data research, which would drive increased investment as a result. There are also opportunities to take advantage of technology to ensure that data collection happens as efficiently as possible, without impacting patient care or creating additional work for medical professionals.

3. Challenges

However, challenges on the road to establishing or maintaining Scotland's leadership in these areas of competences are significant.

Competition

International competition is fierce (see Appendix 1). Scotland's competitive advantage in health and care data is quickly eroding as countries (*e.g.* Estonia, Finland, Belgium) or private health systems (*e.g.* Kaiser) with higher or similar population as Scotland have achieved better data quality, integration and accessibility. As years go by, the advantage Scotland has in terms of longitudinal data decreases. For several reasons, Scotland has unfortunately been slow at acting on clear recommendations to improve data quality, integration and accessibility. The data scoping task force produced a 2018 report on building capability to assess real world benefits, risks and value of medicines (The "Andrew Morris" report[6]). The task force made five main recommendations:

1. Develop a complete record of medicines use across the healthcare system, reliably track which medicines have been prescribed to which patients;
2. Include medicine indication in all prescribing systems;
3. Make access to national laboratory data straightforward and non-duplicative;
4. Better record patient outcomes;

[4] https://www.mobihealthnews.com/news/europe/how-stakeholders-should-push-digital-health-services-fight-covid-19
[5] https://topol.hee.nhs.uk/
[6] https://www2.gov.scot/Resource/0054/00540468.pdf

5. Create a learning system of digital health information to support cross national assessment of medicines.

Implementing these recommendations will be a critical step in creating opportunities for industry and improving patient outcomes (see Appendix 3).

The Scottish Parliament Health and Sports Committee's report on "Supply and demand for medicines" published last month, is very critical on progress made to date by the NHS "to implement comprehensive IT systems which maximise the use of patient data to provide a better service" and urge "to consider the IT and data requirements of the NHS across the country in a strategic way and design systems with long term utility as a matter of urgency".

Similarly, research and adoption of artificial intelligence solutions for diagnosis and other health and care purposes is a global focus for both companies and academia.

Business environment

Scotland is not leveraging enough of the potential of its digital sector to address health and care needs. There is a lack of awareness of such needs within the digital industry. There is an opportunity to learn from existing global approaches to resolve this situation[7]. In addition, the digital industry has little familiarity with the regulatory environment inherent to the health and care sector.

A more integrated and efficient mechanism for communicating health and care system needs, providing testing and validations of solutions in clinical or care environment and adopting and deploying successful solutions within the Scottish healthcare system is needed. This ability to demonstrate validation and provide example of adoption at home is essential for commercialising solutions globally. This challenge is often cited by Scottish companies.

Companies also need more support to commercialise their solutions internationally. This includes support to navigate regulations, test, validate and demonstrate the value of their solutions and engage with customers in various geographies**[REDACTED]**

4. Scotland's Strengths

Scotland has significant assets to become a significant player and leader in the digital health area.

Industry

Industrial activity in the digital health area is underpinned by companies operating both in the life sciences and digital sectors.

There are over 200 digital health companies in Scotland - these are defined as companies selling products or services into the health and care market. The digital health subsector, while still representing a small proportion of the life sciences sector has been one of the fastest growing.

In addition, Scotland has a rapidly growing and innovative digital technology company base, with over 9,000 businesses operating in this space. Around 30% provide IT consultancy and software services. Beyond this, capabilities include cyber security, data, AI, fintech, networks and connectivity- all relevant and important to digital health innovation. In light of Covid-19, several companies have already demonstrated an appetite to pivot towards the health market. The sector also has pre-existing mechanisms, such as network integrators and cluster management organisations that help to efficiently understand and engage with the digital supply side ecosystem. This will be useful in exploring collaborations or joint working opportunities that could support the development of complete and secure digital health solutions.

Research, testing and validation

[7] The AVIA network in the United States is an example of such approaches - https://aviahealth.com/

Scotland has leading clinical research, some of the best longitudinal health data in the world, and strong research base in the medical technologies and digital sectors (SICSA network).

Clinical trials are worth £2.7bn to the UK economy and support 47,500 FTE jobs and whilst this is an area Scotland performs well in, there is potential for further growth[8]. Scotland can build on this expertise to become a world-leading testbed for digital solutions in clinical and care settings. If these testing capabilities are combined with support for the Scottish industry to strategically focus on areas where there is greatest need, this puts Scotland in a far stronger position to service key global markets, as well as realise indigenous opportunities.

Catalysed by the £1.3 billion City Region investment, Edinburgh's data driven innovation programme, with the Bayes centre at its heart, combines world class data infrastructure with expertise in data science, informatics, AI, robotics and autonomous systems.

Scotland's universities are already home to centres of excellence in relevant complementary technologies such as blockchain, quantum imaging, IoT, 5G and cybersecurity, with a further £11 million planned investment to develop a cyber security innovation hub in the Tay City Region.

Several innovation and research centres help catalysing industry academia and NHS collaborations including testing and validation of company's solutions in clinical settings:

- The Digital Health and Care Institute (DHI) focuses on developing digital health and care innovations to key Scottish health challenges.
- The DataLab is Scotland's Innovation Centre for data and artificial intelligence aiming to accelerate the journey by fuelling innovation through collaboration, building skills and growing talent, and strengthening Scotland's thriving data science community.
- The Industrial Centre for Artificial Intelligence Research in Digital Diagnostics (ICAIRD) aims to become a world-class centre of excellence focusing on the application of artificial intelligence to digital diagnostics.
- CENSIS is Scotland's innovation centre for sensing, imaging and Internet of Things technologies, working to de-risk and accelerate innovation and overcome technology barriers to achieve business transformation.
- The Precision Medicine Scotland Innovation Centre (PMSIC) is a platform for collaboration linking Scotland's expertise, data assets and delivery infrastructure to accelerate the real-world adoption of Precision Medicine. Analysis of patient data and especially genomics is a key aspect of precision medicine.

Health Data

Scotland's Community Healthcare Index (CHI) number and associated years of health and care data are a key competitive advantage in the field. Exploiting it fully could not only help companies test and validate solutions but allow data-based optimisation of health and care delivery and associated outcomes.

Internet of Things (IoT)

Covid-19 has brought to the forefront the challenges of providing remote care, addressing health inequalities, and the need for efficient management of NHS assets. There is an opportunity to capitalise more fully on Scotland's IoT capabilities to address these challenges. Scotland already has almost 100% IoT network coverage across Glasgow and Edinburgh and developing networks in the Highlands and Islands. Coupled with the expertise of CENSIS to support secure IoT innovation, Scotland could be an excellent test bed for the development of IoT based solutions.

[8] https://www.nihr.ac.uk/news/new-report-highlights-how-nihr-support-for-clinical-research-benefits-the-uk-economy-and-nhs/22489#:~:text=For%20each%20patient%20recruited%20onto,drugs%20replaced%20the%20standard%20treatment)

Policy

Scotland has developed several strategies relevant to the digital health and care transformation. The Digital Health and Care Strategy[9], underpinned by a legal mandate for integrated health and care planning, budgeting and delivery, shows how Scotland aims to use technology to reshape and improve services, support person-centred care, and improve outcomes. A Scottish artificial intelligence strategy is also being developed[10] and should be published in September. The strategy working group focuses on cross-industry themes. The expectation is that industry-led groups might subsequently focus on industry specific action plans where AI can help address key challenges. Both policies should be implemented at pace to ensure Scotland remains relevant within a global health data context.

The above review of Scotland's strengths shows existing or potential distinctive competences in health and care data, artificial intelligence, Internet of Things, and testing and deployment of solutions in clinical and care settings. Scotland has therefore a solid foundation to improve the delivery of health and care for its citizens while developing innovative digital solutions of global commercial value.

[9] https://www.gov.scot/publications/scotlands-digital-health-care-strategy-enabling-connecting-empowering/
[10] https://consult.gov.scot/data-innovation/artificial-intelligence-ai-strategy/

Appendix 1: Maintaining a Competitive Advantage

Scotland will not have the option to opt out of the digital health and care transformation and remain a competitive nation or be able to meet the aspirations and needs of its citizens. Other countries are already recognising the challenge and accelerating activity in this area.
Belgium – considered exemplars in the field of pharmaceutical innovation in Europe, and ranked second in the world in this regard – is clearly recognising the need to maintain a competitive advantage. A strong focus on effective use of data to drive more efficient prescribing practices and support clinical trials are at the core of Belgium's "pact of the future" which outlines their roadmap for working with the pharmaceutical industry. The sense of urgency and lack of complacency is clear, with the pact recognising that even as leaders in this space, Belgium's position is precarious, and that decisive strategic action is required if they are to hold onto their "yellow jersey" in Europe.
Finland has adopted a new law which allows the government to pool decades of high-quality citizens health data in one secure space that can be easily accessed for innovation and research purposes, with France and Germany also looking to launch similar data hubs. The scheme has been highlighted as a role model approach within Europe.
In Estonia, 95% of data generated by hospitals and doctors is digitised. Citizens have digital access to their own healthcare records, prescriptions and the most suitable healthcare professionals. Secure Blockchain technology is at the heart of Estonian digital healthcare, which operates in a wider digital ecosystem of ID, voting and state services.
In the United States, Kaiser Permanente, one of the leading healthcare providers has over 12 million members. Kaiser Permanente HealthConnect is the largest civilian health technology system in the United States. The system allows clinicians to review entire medical records, check lab results, history of medical visits, directly order prescriptions, lab tests and referrals. Kaiser Research Data & Analysis Center supports health researchers in accessing the records for longitudinal and other studies.

Digital health and care transformation is no longer a nice to have, but an essential area of focus that will support innovation and growth within our healthcare industries, more effective and efficient health care services, and better outcomes for patients across all places within our country. This will not likely happen on its own – strategic coordination will be required and whilst the impact of Covid-19 has largely broken down barriers to digital adoption, there are clear challenges around ability to continue to drive this forward in a coordinated way to ensure that Scotland's health industries are able to compete in a fast changing world.

Appendix 2 –Internet of Things (IoT)

Scotland has developing strengths in IoT predominantly underpinned by CENSIS, Scotland's innovation centre for sensing, imaging and internet of things technologies, and supported by work that is underway to develop Scotland's IoT infrastructure.

IoT network coverage of almost 100% has been achieved in Glasgow and Edinburgh, networks are up and running in Argyll and Bute and the Western Isles, with work also underway in the Scottish Borders, Stirling, Perth, Orkney and Aberdeen. With the development of these advanced and extensive IoT networks in Scotland comes the opportunity to use Scotland as a test bed for the development of smart IoT technologies that can provide data insights at low cost.

Pilot projects with direct relevance to health and care are already underway, with many more opportunities that could be explored. In the care field, examples include the use of sensor networks in the home for dementia management and falls monitoring. Work is also underway with NHS Highland to explore how IoT technologies can increase the efficiency of NHS estates and enhance user and staff experience through things like asset tracking, stock management, predictive maintenance and managing patient flows.

There are several drivers which are likely to increase the scale and scope of opportunity in this area going forwards.

- Covid-19 increasing the appetite for healthcare solutions that reduce physical contact and ease the physical burden on healthcare systems. IoT technologies are well suited to remote monitoring applications.
- We are approaching a potential economic crisis, where health and care organisations (often with already stretched resources and limited budgets) will face the need to make even more efficiencies and cost savings. This is coupled with a sharp focus on the need to ensure quality care provision – creating an opportunity for affordable digital solutions. By its nature, this type of technology can be relatively cheap to implement and run (and cost points will continue to lower as the technology becomes more pervasive).
- Analogue systems will be switched off in the UK in 2025. Currently, the remote monitoring market (fall monitoring in particular) is made up of a small number of key players, and solutions are almost wholly based on analogue systems. We can expect the switch over to create market disruption and opportunities for new solutions providers.

As solutions are developed and implemented in Scotland, it's critical that we leverage our collective resources to promote our capabilities, build Scotland's reputation and maximise trade and investment opportunities.

There are however several challenges that could be stifling innovation and adoption of solutions.

- In general terms, security is a major IoT challenge. CENSIS are proactive in this space and are currently leading a two-year programme of activity specifically to focus on the development of innovative IoT security solutions, develop physical IoT security test pilots, and engage with industry on their needs. By facilitating the right partnerships and networks, there is a chance to ensure that we capitalise on innovative approaches to security that could be applied in health and care settings.
- Understanding and access to medical markets, including the ability to navigate regulatory barriers, is also a challenge, and it's recognised that non-medical applications are usually a far easier starting point. Digital companies working in this space could benefit from help in navigating regulatory requirements, or identifying partnerships and mechanisms to allow companies pivoting towards the care market to validate and test new technologies
- Data infrastructure has been a barrier to home health applications. With nowhere to send the data to, companies have historically had to manage the full end to end themselves. This could be an improving picture which will hinge on the development and accessibility of NHS data platforms. The ability to send data straight to the NHS and create new information paths would open up new opportunities for IoT solutions and could also provide another source of rich data sets. Linked to this are the complexities of managing ownership and access to health data (not a challenge unique to healthcare, but one that is particularly tricky in this space due to the very sensitive and personal nature of the information). Ensuring the development of data platforms continues to progress in a coordinated way, with routes for the private sector to engage, coupled with the right security/ethical/legal/frameworks could further reduce these barriers.
- Cultural challenges and adoption can also prove difficult to overcome - both from the perspective of citizens/patients wanting to engage and having trust in the technology, but also the challenge of medical and care providers having to embrace technology or adopt new ways of working. Engaging more closely with the health and care industry and helping technology providers get a clear understanding of market needs, could increase the likelihood of solutions being welcomed and adopted.

Appendix 3: Using Data to Improve the Safety and Effectiveness of Treatments

The data scoping task force has set out clear recommendations for enhancing NHS Scotland's health data capabilities. The actions focus on data gathering that is comprehensive, complete and interoperable, but what does that mean in practice?

- Developing a complete record of medicines use across the healthcare system
- Reliably tracking which medicines have been prescribed to which patients
- Including medicine indication in all prescribing systems across primary and secondary care
- Better recording of patient outcomes
- Making access to national laboratory data straightforward and non-duplicative
- Creating a learning system of digital health information

Being able to understand exactly why medicines are prescribed would improve evaluation and decision making. Having access to high quality data would allow better judgements to be made regarding medicine selection, co morbidities and outcomes. Better recording of patient outcomes would provide insights into the true effectiveness of prescribed treatments.

Together, these actions would provide intelligence to assess the value of medicines, make clinical improvements, carry out research, assess outcomes for new and existing medicines regarding safety and effectiveness, ensure effective use of NHS medicine spend, and overall improve outcomes for patients.

The potential from using data this way has been well demonstrated in the Salford Lung Study. The study, focused on assessing the safety and effectiveness of new asthma treatment, was sponsored by GSK and involved a collaboration of healthcare professionals from eight organisations across greater Manchester, over 4000 consenting patients, 80 GP practices and 130 pharmacies.

What was different?

The study was the world's first digitally enhanced Randomised Controlled Trial (RCT). It used software and systems that integrated the medical records of patients across all their interactions with GPs, pharmacists and hospitals (the reason Salford was selected in the first place was because of the existing infrastructure of integrated electronic health records). The study was able to monitor all hospital admissions, outpatient and emergency department visits, and all primary healthcare contacts, including out of hours activity, and prescriptions of antibiotics or steroids.

This approach meant data was collected quickly, efficiently and securely, and was high quality. The linked systems allowed close monitoring of patients' safety in real time, but with minimal intrusion, and over a shorter timeline. It provided researchers with a breadth of clinical data and insights into the lives of patients and the way they use their medicines and included a broad and inclusive group of patients. This contrasts with conventional RCTs which usually exclude patients with multiple conditions, and are conducted in highly controlled environments, making them less reflective of everyday practice, and less representative of the wider patient population.

The ultimate outcome was that the study showed that patients treated with the new drug had twice the odds of achieving improvement in controlling their asthma compared to their usual treatment, but the opportunities in terms of economic development could be far broader. Dr Hakim Yadi OBE (CEO Northern Health Science Alliance Ltd) noted that the trial had acted as a springboard for Greater Manchester, positioning the region as a hub for conducting clinical trials, creating opportunities for the technology used in the trial to be adopted elsewhere, and would be an attractive hook for inward investment into the region.

There is no reason why Scotland could not achieve a similar outcome, but implementation of the right systems to allow access to high quality data is a matter of urgency. As pointed out in the recent Supply and

Demand for Medicines report[11], if this does not happen quickly, and in a coordinated fashion that allows for long term utility, it will not only be to the detriment of an economic opportunity, but to patient welfare more broadly.

[11] https://sp-bpr-en-prod-cdnep.azureedge.net/published/HS/2020/6/30/Supply-and-demand-for-medicines/HSS052020R6.pdf

Dear LSS members

LSS Governance Group

I am pleased to let you know that Mark Cook has agreed to Chair the LSS Governance Group, taking over from Marie-Claire Parker. This will be in addition to him leading the MedTech subgroup.

I'm also pleased to announce that David Bunton will be joining the Governance group to work with Mark.

We will be looking for another industry member to join the group in time.

My thanks to both Mark and David for agreeing to this.

Stay Safe

[REDACTED]

edinburgh bioQuarter

MINISTER OF TRADE, INVESTMENT AND INNOVATION BRIEFING SESSION

4th March 2020

12.20 – 13.30
Meeting Room 1, NINE, 9 Little France Road, EH16 4UX

Chair – Anna Stamp, Interim Programme Director

PROGRAMME

Attendees:

Adam Christie	Chief Executive Officer, Calcivis
	Economic Development Directorate, Innovation and Life Sciences team, Scottish Government
Ivan McKee	Minister of Trade, Investment and Innovation, Scottish Government
David Ridd	Business Development, Communications and Marketing Manager, EBQ Programme Team
Anna Stamp	Interim Programme Director, EBQ Programme Team

12.20	**Minister's arrival at NINE, introductions and coffee**
12.25	**Presentation by Anna Stamp, Interim Programme Director and Q&A session**
12.55	**Meeting Adam Christie, CEO, Calcivis (tenant company in NINE)**
13.10	**Interview for BioQuarter**
13.30	**Minister's departure**

Website links:

http://www.edinburghbioquarter.com

http://calcivis.com/

SUBJECT: LCS Sector Skills
MEETING DATE: 17/06/2020
AUTHOR: **[REDACTED]**, SDS

For Information	Members are asked to note the content of the paper
~~For Discussion and Decision~~	~~Members are asked to decide on recommendations~~
~~For Approval and Action~~	~~Members are asked to agree to recommended actions in paper~~

Summary: -

1. Business as usual activities - LCS S kills Investment Plan

Although we have had a focus on the pandemic and how we can support businesses recovery, we have continued with several projects.

.

2. School Engagement

The workshop work with 20 industry members, 20 teachers and Educations Scotland is now available nationally through the GLOW network. The work contextualises what industry does in Scotland with links to careers.
https://wakelet.com/wake/xrDjTWEcxMR4iTopHNi36

3. Work-based Learning

We continue to work with the cell and gene therapy catapult to deliver the ATMP Life Science apprenticeships. To date we have 7 companies wanting to host an apprentice starting 2020. We are currently exploring online delivery with training providers.

4. University

Graduate Employability Masterclasses have now expanded across Glasgow, Edinburgh, Dundee and Aberdeen. We are currently in discussions with SULSA and SCOTChem to take over the running of the programme and still look to add to the industry representatives across Scotland.

Ask: Support for workshops

5. Industry

On the back of the successful Regulatory and Quality course we are now in the process of developing industry led competencies in the area that can be embedded into University curriculums.

6. Skills response

With Brian Bathgate stepping down as co-chair of the skills group its been an opportunity to reinvigorate the group. To that end several workshops have been run (pre-pandemic) with the following challenges identified below:

1. Interventions required and more proactive at each point in Pathway
2. Not benefitting for the investment in Colleges and they are not engaging properly with industry
3. Do we need a formal and simply directory for accessing support by industry?
4. Can modern technology support distance and industry based learning?

5. Getting employees ready for industry at all levels e.g. internships, understanding of industry etc
6. Raising the Awareness Agenda of LS & C at all ages?
7. Foresight Forecasting working Group – 10-15 years?

Now with the dramatic changes to the working and skills/training environment over the last few months. Particularly companies considering their growth and training strategies to cope with the pandemic. We are now keen to understand the landscape better and what challenges we face as we re-set and recover. We now want to set a clear 90-day covid response plan for skills/training around the four themes below:

1. Intelligence gathering (where are redundancies taking place and who is hiring?)
2. Mitigation and matching opportunities (Job hub? PACE)
3. Education system (Transitioning out). Support for apprenticeships/college/uni graduates
4. System resilience / opportunities

To date 13 companies have expressed interest to join the call.

Ask: Support for shaping skills/training provision over the next 90 days.

7. Skills Challenges and priorities for ATMP

A skills plan has been put in place using the evidence from the UK cell and gene therapy catapult and several workshops with Scottish industry. The actions within the industry devised plan now need to be prioritised and clear partners and resources identified to realise the plan moving forward. Sone of the key challenges in the areas include:

- Qualified Persons (QPs) hindering moving products through the pipeline for businesses to move forward
- Access to clean rooms for training
- Integrated maths/data processing
- Data security
- Interdisciplinary working (engineering, chemistry, biology, law and bioethics)
- Awareness and training in supply chain and logistics
- Clinical practice in relation to advanced therapies

These are in addition to those skills already identified in the LCS Skills Investment plan such as, GMP, Biomanufacturing etc…

Ask: Industry to prioritise action plan.

Recommendations:

- LSS to consider the asks and contact **[REDACTED]**@sds.co.uk to support activities
- LSS to support the COVID response to skills and training.
- LSS to further support and prioritise the actions set out in the ATMP skills plan

SUBJECT: LCS Sector Skills
MEETING DATE: 17/06/2020
AUTHOR: **[REDACTED]**, SDS

For Information	Members are asked to note the content of the paper
~~For Discussion and Decision~~	~~Members are asked to decide on recommendations~~
~~For Approval and Action~~	~~Members are asked to agree to recommended actions in paper~~

Summary: -

1. Business as usual activities - LCS Skills Investment Plan

Although we have had a focus on the pandemic and how we can support businesses recovery, we have continued with several projects. Namely the Graduate employability masterclasses, Quality and Regulatory Provision and ATMP apprenticeships.

2. Skills response

18 employers came together to discuss the future skills priorities and the impact of COVID on skills and training.

The main areas of focus:

-Showcase the sectors involvement with COVID highlighting careers and case studies

-Greater engagement with the college sector

-Introducing online learning into the education sector

- Numbers of students with a Life/Chemical sciences degree in Scotland getting jobs in the sector

-Internships in the sector

Overarching message that organisations can change and be flexible to respond to COVID-19 but the major concern remains of the threat of a no deal Brexit particularly medicines into Europe and supply chains.

3. Enterprise and Skills Report (COVID)

A report from a sub-group of the Enterprise and Skills Strategic Board contains recommendations for actions and interventions to help mitigate the expected rise in unemployment caused by the COVID-19 pandemic.
https://www.gov.scot/publications/report-enterprise-skills-strategic-board-sub-group-measures-mitigate-labour-market-impacts-covid-19/

Recommendations include:

- Assistance to support employee retention
- Assistance for those facing redundancy
- Training to enable unemployed people to transition into employment
- Helping vulnerable people into employment

4. ATMP skills and training

The ATMP skills and training plan was discussed on 30th July with industry and the priorities in the action plan to be defined by 17th August 2020.

We continue to work with the cell and gene therapy catapult to deliver the ATMP Life Science apprenticeships. To date we have 10 companies wanting to host an apprentice starting 2020. We are currently exploring online delivery with training providers.

5. Digital provision

During 2019/2020 SDS managing and administered the Digital Start Fund on behalf of Scottish Government, with the provision of digital training under an approved provider model.

The Digital Start Fund aims to help people on lower incomes develop skills for digital occupations in order to boost their employment opportunities and reduce the skills gap in this key sector. The fund will be a training grant awards to eligible applicants

https://www.digitalworld.net/study/digital-start-fund

LinkedIn, Microsoft, and GitHub are offering free learning paths mapped to jobs that are in-demand, discounted Microsoft certifications to validate skills, and best practices for job searching and interview prepping

https://opportunity.linkedin.com/en-us

Recommendations:

- LSS industry members to come forward with detail on what work they have developed in response to COVID contact **[REDACTED]**@sds.co.uk
- LSS to further support and prioritise the actions set out in the ATMP skills plan