TRUSTECH

Scottish Enterprise

Research to inform a review of how Scottish Enterprise and partners can unlock the full potential of digital health opportunities for Scottish SMEs

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Executive Summary

This commission was intended to help inform a review, led by Scottish Enterprise, to consider what Scottish Enterprise and partners can do to unlock the full potential of the digital health opportunity, including, but not exclusive to, exploring the merits of cluster building approaches which connect companies to available support and help mitigate barriers to SMEs entering growing digital health markets.

The two work packages completed by Trustech examined (i) economic development interventions outwith Scotland focussed on supporting digital health industries, or healthcare through digital technologies and (ii) barriers to digital companies (SMEs) in Scotland entering digital health markets.

The first work package identified common elements across the most impactful programmes:

- A structured **selection** programme with key stakeholders from representative bodies
- A tailored **education** programme to meet the specific needs of the company
- A dedicated **navigator** with a combination of relevant health system and commercial experience to support the company from programme entry to adoption at customer sites.
- An **evangelical partner** within target organisations
- A pilot programme to inform **Health Economic Assessment**
- Preparation of a customer appropriate **business case**
- Qualified introductions to **potential commissioners** of service
- **Signposting** to other support networks primarily within the localised innovation ecosystem

The second work package, based on a small survey (n=9) of SMEs, identified significant challenges over and above already identified challenges to entering and operating in the digital health sector.

Given the strength of feedback, if digital health is perceived to be a key economic growth sector in Scotland, more work is recommended to fully understand and explore the issues. On the basis of the SME survey it was recommended that support programmes should provide a full understanding of the additional challenges and barriers facing digital health companies, and upskill participants in topics such as: -

- securing early evidence of innovation benefit and health economics studies;
- health and social care organisation structures across the UK;
- procurement and commissioning;
- data security and data governance requirements;
- software medical device regulations;

and include:-

- a focus on the extreme challenges of the sector;
- early triage by appropriate sector experts to calibrate expectations;
- strategies for generating alternative income;
- recalibration of assumptions regarding investment funding;
- accessing digital health markets outwith Scotland,
- support to secure reference customers.

There would appear to be significant commonality and crossover between the methodologies and structure of the exemplar programmes and the identified actions arising out of the SME survey work.

Introduction

TRUSTECH have been commissioned by Scottish Enterprise (SE) to provide Digital Health Research Services following an invitation to respond to a tender on the 17th March 2021.

This commission is intended to help inform a review, led by Scottish Enterprise, to consider what Scottish Enterprise and partners can do to unlock the full potential of the digital health opportunity, including, but not exclusive to, exploring the merits of cluster building approaches which connect companies to available support and help mitigate barriers to SMEs entering growing digital health markets. The review by Scottish Enterprise will focus on three key areas:

1. Strategic i.e. Identification of digital health strategies in other countries and their relevance to Scotland as established leaders or in rapidly gaining market share. Also, engagement within Scotland with strategic stakeholders (please note this workstream area will be undertaken by Scottish Enterprise and is out with the scope of this commission*).

2. Operational i.e. Economic development interventions focussed on supporting digital health industries, or healthcare through digital technologies.

3. Barriers to digital companies (SMEs) in Scotland entering Digital Health markets.

The focus of the Digital Health Research Services commission is on Operational (2) and Barriers (3), and this informs the approach we have taken, the research and interviews completed and the structure of the report.

To establish a baseline for exemplar intervention programmes and also to inform the interviews with SMEs, we completed a review of the existing support provided across Scotland and supplemented our findings by conducting interviews with representatives from key stakeholders.

The project supports the wider work of Scottish Enterprise to unlock the full potential of digital health opportunities by identifying the barriers to entry for SMEs and identifying how future interventions and investment could be most effectively deployed, resulting in greater collaboration and growth. To ensure the research completed the specification, we provided a detailed scope of works, split into four work packages with agreed milestones.

- WP1 Research successful economic development interventions outwith Scotland focussed on digital health.
- WP2 Within Scotland, engage with SMEs to identify any perceived challenges and barriers to considering and entering digital health markets.
- WP3 Reporting to include production of research paper and presentation to selected stakeholders from Scottish Enterprise and key partners.
- WP4 Project Administration

Research successful economic development interventions outwith Scotland focussed on digital health.

The desk based research and engagement with key partners was commissioned as the first work package, and sought to identify core components, skills and strengths of exemplar economic development programmes supporting SMEs with a primarily digital offering seeking to access the Healthcare market in the associated region.

The commission also required that programmes with the potential for future collaborations or partnerships with Scottish Enterprise, or those that could be referenced as a model for exemplar programmes by Scottish Enterprise should be identified.

Programme Selection

Our initial research of the market identified a multitude of economic development intervention programmes that met the specification stipulated. To ensure we could efficiently identify those that would be of most value to inform the wider research of Scottish Enterprise, we first undertook an exercise to establish a baseline of the current support available to Scottish Digital (Health) SMEs from organisations across Scotland.

The initial long list of 30 programmes across the UK, Europe and further afield, was reduced to 19 programmes that, on further research, more closely aligned with the criteria stipulated by Scottish Enterprise.

After completing our desk-based research, we have presented the nine programmes that most closely matched the criteria, showed a willingness to work collaboratively and had impact or success that closely aligned with the criteria. Where possible we complemented our desk-based research with a structured interview with a key team member to provide a greater degree of insight into the impact of the programme, the wider support ecosystem and provide clarity where required.

Given the specific nature of healthcare in the UK, our research is dominated by programmes from across the rest of the UK, however we have included programmes from further afield if we felt their approach was innovative or impactful.

With a few exceptions the majority of programmes, regardless of geographic location, were supported by funding from the public sector – be that European, National, Local or Regional.

Key Criteria

Programmes were considered from the perspective of (i) the programme's objective and (ii) the companies supported by the programme and reviewed key elements across the programmes.

Firstly, what did success look like from a **programme level** and what were the programme features, benefits, and impact:

> **QUALIFICATION:** How were companies selected – against what criteria/what due diligence? What stage were the companies at (pre-start up, start-up, scale-up, IPO, etc…)
>
> **BUDGET & TIMESCALES:** What was the budget for the programmes and over what timescale has the programme run?
>
> **PARTNERS:** Who are the core partners/key stakeholders and what was their role in the programme?
>
> **IMPACT:** How was success defined (programme/company level), is this evidenced in use cases? Is there any evaluation data on the impact of the support programme?

Secondly, what did success look like from a **company level** and what were the programme features, benefits, and impacts:

> **SUPPORT:** What support was offered? What collaborations were there? What component of the programme was educational, introductions, market readiness and funding?
>
> **IMPACT:** Did it deliver a definite Patient Benefit? Was there an impact on the finances of the company? Has this advanced the product/service along the "TRL"? Was the company commissioned or procured by a healthcare provider(s)?
>
> **OTHER:** Were there any other factors contributing to success?

Common Elements to Exemplar Programmes

Regardless of the nature of the funding there are common elements across the most impactful programmes:

- A structured **selection** programme with key stakeholders from representative bodies
- A tailored **education** programme to meet the specific needs of the company
- A dedicated **navigator** with a combination of health system and commercial experience to support the company from programme entry to adoption at customer sites
- An **evangelical partner** within target organisations
- A pilot programme to inform **Health Economic Assessment**
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DigitalHealth.London

Summary	DigitalHealth.London (DHL) is a well-regarded localised cluster focused on accelerating the adoption of digital health solutions into the NHS, with impact evaluated against well-defined economic goals. The Accelerator provides a tailored support programme to selected cohorts over 12 months to develop, test, and pilot their innovations within the NHS.
Established	A review commissioned by the London Health Commission in 2014 recommended that the Department of Health, the Department of Business, Innovation and Skills, and the National Institute for Health Research should invest in an Institute for Digital Health and Accelerator for London, coordinated by MedCity and the AHSNs.
Funding	Supported by NHS England, the (London) Mayor's Office, CW+ (Chelsea and Westminster NHS FT Charities) and part-funded through the European Regional Development Fund.
Key Partners	Medcity (AHSC), UCL Partners (AHSN), Imperial College Health Partners (AHSN), Health Innovation Network (AHSN), NHS England, The Mayor's Office (London), CW+, RYSE Asset Management, UK Israel Tech Hub.
Support Provided	DHL provides two support programmes – ACCELERATOR and LAUNCHPAD. ACCELERATOR programme companies are allocated an NHS Navigator to provide bespoke advice, guidance, and support, to help companies navigate the complex NHS environment and improve their chances of success. This support is complemented by a comprehensive educational support programme of over 30 events, covering 10 core areas including evidence generation, information governance, commercialisation, and communication. Each cohort consists of companies at different stages of maturity, from "Early Stage" to "Market Ready" and with differing support requirements, with support tailored to the needs of each company. The LAUNCHPAD programme was launched recently to support companies that had applied to the ACCELERATOR programme but were unsuccessful. The programme runs cohorts of 5-8 companies and provides intensive support over a 3-month period.
Selection Criteria	Selection of SMEs can take up to 6 months and is measured against NHS priorities, financial metrics, and clinical metrics by a panel of stakeholders drawn from the key partners and supplemented by other industry experts. Each cohort attracts 130-180 applications of which a maximum of 20 companies are selected.
Impact	The programme has been running since 2015 and at last recording had led to £64M investment raised for companies, £76M savings to the NHS and 22.2M (opportunities) for patients to benefit. It has formed 36 new research collaborations, created 23 fellows and 45 mentors, transformed 18 pathways, and introduced 12 third party digital solutions.
Key Learning	A key differentiator is the role of the NHS Navigator. NHS staff are seconded to work as NHS Navigators, each providing c.100 hours support per year to five companies. Navigators with commercial experience are now also recruited from outside the NHS.

	MSc Health Economics students from University College London (UCL) and King's College London are matched to companies through a rigorous selection process to complete a summer internship, working with allocated companies to develop an NHS level health economic impact assessment. This is of great value to the student and the company. The DHL alumni network is self-sustaining, utilising the Slack platform for effective communication, with DHL organising events and providing ad hoc support.
References	Accelerator Independent Evaluation 2020 DHL Impact Report 2019

Wayra Health Hub 2020

Summary	Founded in 2020 as a direct response to Covid-19, the Wayra Health Hub 2020 aims to empower and enable health-tech companies to accelerate innovative solutions which can address key challenges in the healthcare sector. The Health Hub provides founders with the opportunity to connect and collaborate with leading health experts and decision makers from Novartis Biome UK, the NHS, and the wider health and tech ecosystem to grow their digital health start-up and to provide solutions at scale.
Established	Building on the existing relationship between Wayra UK and Novartis Biome UK to address key challenges in the healthcare sector, the Wayra Health Hub 2020 was formed to find solutions that could support the NHS as it deals with the medium to long term challenges created by Covid-19 and beyond.
Funding	The Wayra Health Hub 2020 is based on the well-established Wayra model, part of the Telefonica Open Innovation Family. Entrants to the programme receive an "Investment" from Wayra into their company in the form of a "convertible loan note" – a proportion of this investment is to fund the "services" provided by the Wayra Health Hub 2020 Programme.
Key Partners	The Health Hub is a partnership between Wayra UK and Novartis Biome UK, it states the programme is co-designed with the NHS.
Support Provided	**Access to the Novartis network** A customised induction day tailored to the start-up's growth needs at Novartis. Access to coaching and 1:1 engagement with Novartis subject matter experts from functions such as marketing, commercial, market access strategy, health economics and medical affairs. Access to a single point of contact to provide support and guidance via a Strategic Partnership Lead. **Support with NHS Engagement** Understanding and navigating the NHS, to enhance knowledge and insights into the NHS.

	Accessing innovation masterclasses and associated programmes via the AHSNs to enhance growth opportunities. Identifying senior NHS leaders as mentors and for 1:1 engagement for practical advice and guidance. **Wayra Support** Wayra's Investment, access to the Wayra Investment network and office space.
Impact	The programme is still in its early stages and any impact is limited to the case studies provided (Test Card). We have researched the other more established Wayra programmes to identify the impact.
Selection Criteria	There is limited information available on the selection criteria for access to the programme and we were unable to engage with contacts at Wayra and therefore unable to complete an interview with the Programme Lead to establish a more detailed understanding of the programme. The programme was looking to work with companies who can accelerate and scale digital health solutions that will support the NHS to deal with the medium to long term challenges created by Covid-19.
References	Wayra Health Hub 2020

Life Sciences Hub Wales

Summary	LSHW is a well-established national programme with a clear mission to help the people of Wales benefit from improved healthcare and economic wellbeing by working with innovative companies to find solutions for NHS and healthcare providers.
Established	The Welsh Assembly appointed a task and finish group to review the strategy of LSHW in 2018 – this led to the introduction of the Accelerate programme.
Funding	Co-funded by the European Regional Development Fund, the Welsh European Funding Office and Welsh Government's Health and Social Services group, with impact evaluated against well-defined economic goals.
Key Partners	Business Wales, NHS Wales Informatics Service (NWIS), Swansea University (Health Technology Centre (HTC) and AGOR IP), University of Wales Trinity St David's (Assistive Technologies Innovation Centre (ATIC)), Cardiff University (Clinical Innovation Accelerator (CIA)) and The Bevan Commission.
Support Provided	LSHW is a facilitator, enabler and connector, engaging with 100-130 companies per annum through two key programmes (DHEW and Accelerate) with tailored support provided by key partners and the several inter-related national programmes (DigitalHealth.Wales, SMART Innovation, Technology Enabled Care Cymru). **Digital Health Ecosystem for Wales (DHEW)** is a collaboration between Life Sciences Hub Wales and the NHS Wales Informatics Service (NWIS), and is funded through the Welsh

	Government's Efficiency through Technology Programme. Selected companies have access to NHS Wales systems and data through a platform of APIs, reducing development time and ensuring products are better suited to NHS Wales' needs, and can share that information across Wales. **Accelerate** helps innovators in Wales to translate their ideas into solutions that can be adopted in health and care. Companies are matched with tailored funded resources from across the ecosystem. In 2017 NWIS (NHS Wales Informatics Service) launched an innovative digital health Dynamic Purchasing System (DPS) framework with a clear purpose to support innovative companies to create solutions and support the development of emerging technologies with clear objectives. Wales has ten Research, Innovation and Improvement Coordination Hubs (RIICs) aligned with each of the seven health boards and three specialist services.
Impact	Since 2018 DHEW has supported 29 major projects, linked 285 organisations and individuals, and held 23 ecosystem events. Good examples of adoption across Welsh health boards are DrDoctor and PatientKnowsBest.
Selection Criteria	Companies are evaluated on a case by case basis against the identified priorities of LSHW and the support required by the company. LSHW will identify a tailored and appropriate support programme drawing from the established resources of key partners.
Key Learning	The main challenge is the market adoption gap with the seven health boards deciding which services they require at a local level. This gap closed with the introduction of the DPS. Digital Health companies that engaged with LSHW and were matched with an "evangelical senior stakeholder within the NHS" had shown a good level of adoption and spread.
References	Life Sciences Wales Brochure

Health Innovation Manchester – Innovation Nexus

Summary	Health Innovation Manchester (HInM) is a regionalised Academic Health Science Network (AHSN) serving Greater Manchester, and is part of the England wide Academic Health Science Network – a national healthcare innovation cluster. HInM consists of GM ASHN, Manchester Academic Health Science Centre (MAHSC) and the NIHR Applied Research Collaboration (ARC-GM). It works closely with the GM Health and Social Care Partnership (GMHSCP) and Greater Manchester Combined Authority (GMCA).
Established	A report by the CEO of NHS England in 2011 led to the UK Government announcing the need for an academic health science network. In 2013, fifteen regional AHSNs were created to spread innovation at pace and scale – improving health and generating economic growth.

Funding	The Innovation Nexus and associated SME support is funded by a combination of NHS England, Office for Life Sciences, and match funding from ERDF.
Key Partners	GM based NHS Commissioner and Providers, GM Research Groups, GM Universities, NHS England, Office for Life Sciences, Growth and Investment agencies and commercial partners.
Support Provided	The Innovation Nexus team provide bespoke advice on the step's companies should be taking to progress their innovation and engage with the NHS. This includes access to a dedicated and experienced Procurement Specialist. Support consists of two core programmes, "STEP INto Health" and "Research and Innovation Health Accelerator" (recently launched). The **STEP INto Health** programme is a mature programme designed to help companies prepare for selling into the life sciences market. It is primarily an education and introduction programme, providing access to networks, strategic knowledge, and market opportunities, through one-to-one support and several workshops with leading industry experts. The educational aspect of the programme, normally delivered through a series of workshops has moved online due to Covid, and consists of several modules including an overview of the GM Landscape, Procurement in the NHS, Understanding Social Value, Developing a value proposition and NHS business case, with a range of supporting sessions delivered by external specialists (e.g. Funding and Grants, Brexit). Companies that complete the STEP INto Health programmes will have worked with specialists to develop a Health Economic case and refined their pitch in preparation for a presentation to the GM NHS Heads of Procurement (HOPs) group. Health Innovation Manchester runs a grant funding programme "The Momentum Fund" to support the adoption and spread of needs-led, evidence-based innovations in the health and care system, with funding up to £50,000 per company.
Selection Criteria	Companies are selected for the STEP INto Health programme by a panel of key stakeholders and industry experts against key criteria including postcode, SME status, support required and expected outcomes.
Impact	Within the 2019/20 impact report it was identified that 44 companies had completed the STEP INto Health course, over 200 SMEs had been separately supported by the team, and 77 new jobs had been created with £2.68M funding leveraged for SME development.
Key Learning	Significant efforts have been invested in the selection of companies for the STEP INto Health programme, combined with the information imparted throughout the course by NHS and industry experts and a clear outcome: an opportunity to present a refined business case to procurers across GM resulting in adoption and spread within region, and ensure market ready solutions across the wider ecosystem (National ASHN Network – Innovation Exchange)
References	Our Documents - Health Innovation Manchester

National Innovation Accelerator

Summary	The NHS Innovation Accelerator (NIA), is an award-winning national accelerator supporting dedicated individuals ('Fellows') to scale their high impact, evidence-based innovations across the NHS and wider healthcare system. The NIA aims to help create the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically in the NHS, deliver innovation into practice for demonstrable patient and population benefit and learn from Fellows' experiences so that others benefit from knowledge generated.
Established	The programme was launched by NHS England Medical Director in July 2015 to support delivery of the Five Year Forward View and was more recently highlighted in the NHS Long Term Plan to develop and spread innovations across parts of the NHS.
Funding	The NIA is an NHS England and NHS Improvement initiative delivered in partnership with all 15 Academic Health Science Networks across England, hosted at UCL Partners.
Key Partners	NHS England, NHS Improvement, NHS Digital, AHSN Network, NICE, The Health Foundation.
Support Provided	**Support:** The NIA provide day-to-day support, networking, and introductions **Signposting:** Key partners provide signposting and local insight and introductions **Mentoring:** Drawn from an impressive pool of mentors and tailored to the Fellow **Community:** The alumni of the programme provide peer-to-peer support **Learning:** A tailored education programme of information sessions and learning events **Bursary:** Funding to help the Fellow scale their innovation across the NHS
Selection Criteria	Each year the NIA invites applications from exceptional individuals representing innovations which address clear needs and challenges faced by the NHS. All applications undergo a robust, competitive, multi-stage process involving a college of expert assessors drawn from the key partners. The selection process is in five parts: • Application Screening and Assessment (reviewed by 5 assessors) • NICE review (informal review by NICE, NHS England and NHS Improvement) • Interview by a representative panel of key stakeholders • Decision making panel chaired by Professor Stephen Powis • Due diligence: references, finances, IP, and Information Governance.
Impact	Since the first cohort in 2015 the NIA has supported 49 Fellows with 52 innovations, led to 2,304 additional NHS sites using NIA innovations, delivered £38 million in savings to the NHS, raised £154.4m external funding, created 523 new jobs and won 120 awards with 49 NIA innovations selling internationally. The impact of this exemplar programme is further evidenced in the numerous case studies.
Key Learning	This is a well-regarded and impactful programme, and significant effort is invested in the selection of Fellows for each cohort to ensure that the expectations of the applicant are a

	good match with the programme. The Fellows are then supported by the wider NHS network and industry experts, with funding available to drive the adoption and spread.
References	NHS Accelerator Achieving scale and spread NHS Innovation Accelerator: 2021 Intake Call for Applications (September 2020)

Assistance Publique - Hôpitaux de Paris, France (AP-HP)

Summary	The Assistance Publique - Hôpitaux de Paris (AP-HP) is a public health group consisting of 39 hospitals in Paris and the surrounding regions, employing over 100,000 people.
Established	The AP-HP tech transfer and innovation division was established in 1992 with a remit to "invent, value and care". It is a core part of the AP-HP hospital group.
Funding	Since its launch in 2016, the Foundation has raised €20M for research through donations, grant and income derived from the provision of expert research services. PULL projects are sponsored by an AP-HP hospital and draw funding from government (maximum of 120% available). PUSH projects are sponsored, and part funded by the commercial partner with additional funding available through government. Coalition Next projects draw funds from a range of sources, appropriate to each innovation project; collectively referred to as the "PharmaTech Venture pool"
Key Partners	AP-HP has strong working relationships with national and regional governmental bodies and industry partners. It is a founding partner of the Coalition Next initiative formed of public and private partners working together (pro bono) to accelerate innovative health projects into healthcare institutions.
Support Provided	Historically AP-HP has approached innovation partnerships from a PULL or PUSH perspective that meet the strategic priorities of AP-HP, although they also have the remit to work with innovations that are "interesting". **PULL:** AP-HP will work with a Clinician/Physician to address an unmet need ("answer a question"), they will identify appropriate commercial partners to meet the clinical need and form a project team to evaluate the innovation with a view to onward procurement. **PUSH:** Companies will approach AP-HP with an innovative solution, this will be critiqued against the strategic priorities and if it is decided to be a good fit then a clinical partner will be identified. More recently they have been utilising the Coalition Next initiative, where appropriate, to accelerate their innovation projects.
Selection Criteria	The Coalition Next initiative has a three stage selection criteria:

	Selection: All application are reviewed by all coalition members against beneficiary needs specification. **Funding:** The project is presented at a Deployment Committee to agree the most appropriate sources of funding via the PharmaTech Venture pool. **Deployment:** Once funding is secured the project is rolled out to identified institutions, monitored, and supported by the Coalition Next.
Impact	Since its launch in 2016 the Foundation has raised €20M for research and funded 120 teams or projects in all fields of research (biotherapies, oncology, epilepsy, urology, artificial intelligence, diabetes, etc.).
Key Learning	The approach of AP-HP combines a structured PULL/PUSH approach to innovation adoption aligned with the strategic priorities of the hospital group with a clearly defined sponsor and clinical lead. It draws funding support, up to 120%, from a range of sources as appropriate for the project. It also allows flexibility for the exploration of "interesting innovations" and leverages the knowledge and experience of commercial and investment partners.
References	APHP Business Report 2018 (French)

Alsace Biovalley (French Cluster)

Summary	The BioValley France Competitiveness Centre unites and supports start-ups, SMEs, large groups, healthcare, research and training organisations from the Grand Est region around the health theme. Its "pharma / biotech" and "medical technology" experts identify new business growth opportunities, financing and innovation.
Established	Alsace Biovalley is one of seven mature French health competitiveness clusters; Alsace Biovalley, Atlanpole Biotherapies, Cancer-Bio-Santé, Eurobiomed, Lyonbiopole, Medicen Paris Region and Nutrition-Health-Longevity, established in 2004 following a competitive selection process led by inter-ministerial committee.
Funding	Funding for the cluster is primarily drawn from public funding bodies: Direction Generale Des Entreprises (National Directorate), The European Union, Grande Est Regional Authority, Mulhouse Alsace Agglomeration, Colgar Agglomeration (Local Authorities), The Strasbourg EuroMetropole.
Key Partners	Cluster partners are drawn from industry (Sanofi, Merck), investors (Alsace Business Angels), ecosystem (Alsace Digital), governmental bodies (Business France) and academia (University of Strasbourg, University of Lorraine).
Support Provided	The service offer is tailored to healthcare players focused on the four priority areas (Drug Discovery, Medical Technologies, E-health and Diagnostics) and covers the following areas: **Business Competitiveness:** Emerging Innovation, Calls for Projects, Evaluation

	International Action: International Accelerator, Trade Missions **Innovation Projects:** Legal and regulatory support, Grant writing
Selection Criteria	Selection of member companies to the cluster is measured against: • Alignment with the strategic priorities of the cluster • Scientific positioning of innovation • Project plan and management controls • Intellectual property • Economic impact • Due diligence: business plan and financial sustainability
Three Country Cluster	The Alsace Biovalley is fairly unique in that it operates trinationally (France, Germany, and Switzerland) with an established ecosystem in each of these countries, supported by 14 associated Technology Parks including the Nextmed (Strasbourg) Campus. The Basel region is one of the world's leading biopharma centres. With the ecosystems of Strasbourg, Freiburg, Mulhouse, and Zurich it sits at the heart of a region of biopharma, industrial, scientific, and technological expertise. The uniquely located programme also opens up opportunities for cross border project calls as evidenced in the recent Call for Franco-German bilateral artificial intelligence projects
International Focus	There is a clear focus on leveraging the trinational nature of the Alsace Biovalley and its strategic location for the benefit of the SMEs the teamwork with. The directory of members shows a multitude of companies at different levels of maturity, and we have selected a few to demonstrate the impact of the programme: Dianosic – Strasbourg based start-up has gained CE marking for its Medical Device CAVIT and secured funding in 2020 to expand into its identified markets: Europe, United States, Japan, and China. D2D (Doctor to Doctor) – Strasbourg based, the Doctor To Doctor team has been working full-time on the project since 2019 and has stated its intentions to grow the company in the international market. Biosynex - founded in 2005 and based in Strasbourg, Biosynex specialises in the design and distribution of rapid diagnostic tests (TDRs) with a turnover in excess of €35M in 70 countries with c.29% of turnover coming from exports.
References	Member Directory Key Projects

Estonian HealthTech Cluster – Connected Health

Summary	Connected Health, founded by the Science Park Tehnopol, is a country-wide partnership of 80+ partners committed to accelerating the adoption of connected health solutions.
Established	Building on previous Estonian Research and Development and Innovation strategies, there were several strategic documents produced at the instigation of the national government from 2013 onwards that led to the ultimate formation of the Estonian HealthTech cluster, including (i) the Estonian eHealth Strategy (2015); (ii) Estonian Research and Development and Innovation Strategy 2014-2020 (2014) and Smart Specialisation – Activities: Analysis of Bottlenecks and New Opportunities (2013).
Funding	Connected Health receives ERDF Matched Funding.
Key Partners	The Connected Health Cluster consists of: • Commercial partners (start-ups, health IT, medtech, biotech, and pharma) • R&D partners (universities and technology competence centres) • Health and wellness service providers • Patient organisations and user communities • Public sector organisations (ministries responsible for healthcare and entrepreneurship, national health insurance, and the national health development agency). The cluster is also part of the European Connected Health Alliance and ScanBalt network.
Support Provided	Connected Health acts as a broker between several parties in healthcare (health tech start-ups, needs-based partners, i.e. hospitals and patient organisations, and IT companies) to create new services and products that help solve problems related to healthcare. Estonia has overcome a culture challenge present across the UK with its well established nationwide e-health infrastructure and an inherent trust in technology for the benefit of all. With this significant hurdle overcome, the CH team can focus on brokering relationships and encouraging innovation to flourish. This is reflected in the core components of their current strategy (2019-2023): • Strategic goals are set by key stakeholders • Critical processes must work so that the goals can be achieved • Organisational capability must be sufficient and sustained • Financial capacity must be maintained.
Selection Criteria	To be accepted as a cluster partner they must demonstrate the following: • Work as part of a team to develop or improve existing solutions to healthcare problems • Are familiar with their target markets, have international visibility and market their products and services together • Visibility of the international market opportunity.
Impact	Whilst we have not been able to identify an independent impact assessment, the "Stories" (Case Studies) on the Connected Health site of successful innovations deployed across Estonia and many international deployments are numerous.

Key Learning	A national e-health infrastructure allows innovators and clinical teams to work together on solutions that can be rapidly deployed across the nation. This influences both the distinctly different support provided by Connected Health and the considerable impact they are having.
International Focus	An internationalisation strategy is a key tenet of successful innovation projects, stipulating that any digital solutions can be deployed in Estonia as well as on foreign markets. Start-up companies can receive an investment of €10,000 to support their efforts in securing seed funding or developing sales in the export market.
References	Learning from the Estonian e-health system Estonia built one of the world's most advanced digital societies

Singapore National Health Innovation Centre

Summary	NHIC Singapore supports the publicly funded clinical research sector of Singapore to accelerate healthcare innovation towards a market-ready product. Established in 2014, they support the development of innovative technologies and services to improve healthcare delivery and patient care.
Established	The National Health Innovation Centre (NHIC) was initiated by the National Medical Research Council of Singapore (NMRC) and is the designated Innovation and Enterprise Office (IEO) for public hospitals, public health institutions and national specialty centres.
Funding	Funding varies by grant; however, grants are jointly funded by NHIC, National University Health System, SingHealth and National Healthcare Group, Singapore Health Assistive & Robotics Programme (SHARP) Grant and Enterprise Singapore.
Key Partners	NHIC is partnered with all three of the healthcare clusters in Singapore, covering all publicly funded hospitals, public health institutions and national speciality centres. Other partners include academic partners e.g. National University of Singapore and supporting partners e.g. Enterprise Singapore, SMART Innovation Centre.
Support Provided	The NHIC team members have strong track records in the identification and commercialisation of intellectual property from academic, clinical, and commercial fields. NHIC adds value by adopting an active role in the mentoring of applicants and their respective teams at all stages. NHIC brings in specialist consultants to assist with regulatory information, business development and other business activities, as needed by the individual projects.
Selection Criteria	NHIC has three funding streams for projects which address an unmet healthcare need and have demonstrated 'proof-of-principle' supported by experimental data. Each scheme targets different stages of the innovation development pipeline and all proposals for funding

	must address IP management, commercialisation strategy and public health impact of the innovation. Collaborations with industry are encouraged if they strengthen the proposal. **Innovation to Protect** (I2P): funds expenses to protect patentable innovations with significant healthcare impact and commercial potential. **Innovation to Develop** (I2D): for a deliverable development plan to take an innovation to a commercialisable endpoint. **Innovation to Industry** (I2I): for projects which have successfully completed I2D funding and which, in conjunction with an industry partner, require co-development in order for the industry partner to license the technology. **Innovation to Startup** (I2Start): streamlined funding pathway bringing together three successful grant schemes to support company formation around medical technology innovations (TRL3+).
Impact	There are several case studies available on the website demonstrating impact • Robotic Sock for DVT and Ankle Joint Contracture • aiTriage™
Key Learning	The impact of a structured approach to support, providing appropriate funds at each stage of development with a clearly defined outcome (market-ready product) is demonstrated in the multitude of projects.
References	NHIC Success Stories

Observations

There are several common elements across the most impactful programmes, regardless of geographic location or source of funding, that we believe have led to programmes with a real and sustained impact:

- A structured **selection** programme with key stakeholders from representative bodies
  - Significant effort was invested in the selection process with clearly defined qualification criteria reviewed by an experienced evaluation panel with representatives drawn from healthcare, industry, academia, and patient groups.
  - Focus on innovations that closely align with strategic healthcare priorities of the region, utilising a blend of PULL (clinical sponsor) and PUSH (company sponsor), whilst allowing flexibility to support "interesting innovation".
  - Focus on a small cohort of well qualified, well selected companies, building an alumni network to provide peer-to-peer support.
  - Complete a thorough due diligence of all companies engaging with the programme, covering references, finances, IP, and Information Governance.
- A tailored **education** programme to meet the specific needs of the company.
  - Provide a clearly defined, structured programme of support to companies that is flexible enough to be tailored to meet the agreed development needs of the company.
- A dedicated **navigator** with a combination of health system and commercial experience to support the company from programme entry to adoption at customer sites.
  - Provide dedicated "navigator"-type support to companies for the defined duration of the programme, ensuring "navigators" have experience across both healthcare and commercial, with proven relationship management, problem solving and project management experience.
- An **evangelical partner** within target organisations.
  - Invest effort in the preparation of companies for any selection process by utilising key partners (public and private sector) to ensure that time and resources invested by the company in any selection process is worthwhile.
- A pilot programme to inform **Health Economic Assessment**
  - Engage with academia for the provision of specific support services, e.g. Health Economics Impact. This is beneficial for both the company and the student.
- Preparation of a customer appropriate **business case.**
  - Utilise appropriate procurement tools to facilitate the sustained contracting of services against a clearly defined specification, realistic time to market and supportive payment terms.

- Qualified introductions to **potential commissioners** of service
    - Have a clearly defined output: a sustained contract for the procurement of products/services by multiple healthcare organisations in the region.

- **Signposting** to other support networks primarily within the localised innovation ecosystem
    - Have one clearly identified organisation, with decision making/procurement authority, that sits at the core of the economic development initiative and draws from the resources of the wider system.

The key differentiating factor between a programme that is **considered to be impactful** and one that **is impactful**, from the perspective of the SME, the funder, the Programme team and the wider ecosystem is where the support provided led to the **onward and sustained procurement of the product/service.**

Focus on International Markets for Growth

One of the key elements of the exemplar programmes, outside of the UK, was a focus on international markets as an opportunity for growth, from a relatively early stage in the company evolution. This has been included in the programme summaries of the preceding pages where this was felt to be particularly impactful (Alsace Biovalley and Estonian HealthTech Cluster – Connected Health).

The UK based programmes that were reviewed, including the short list, did not overtly reference international markets as a growth opportunity. International engagement was orientated towards bringing companies to the UK, as evidenced in the National Innovation Accelerator, or to form collaborations with international organisations to further research or strengthen strategic relationships.

Perceived challenges and barriers for SMEs considering and entering digital health markets.

The SME survey was commissioned as the second work package element in a wider survey looking at the SME Digital Health sector in Scotland and its growth challenges and economic development potential.

The survey sought to identify, through discussion with a small number of SMEs in the digital health space, the challenges to entering and operating in the digital health market over and above those faced by SMEs operating in other markets.

Company Selection

SMEs were selected for interview from a longlist supplied by Scottish Enterprise and key sector partners. All SMEs were pre-identified as operating in or interested in operating in the digital health sector.

From the longlist, a shortlist of 10 companies was selected for a 30-minute phone interview, with ultimately 9 interviewed as one was not available within the report timescale. The shortlist was selected to include four broad categories of companies to give a range of views and perspectives.

- Established later stage businesses with evidence of product traction based on news releases; this category included businesses with sales in other non-health sectors.
- Venture capital backed SMEs taken as a proxy for prospective growth potential.
- Non-venture capital backed SMEs.
- Very early stage or very small businesses representing SMEs at the start of development or where the business had perhaps never developed beyond the founding directors.

Most of the companies interviewed reported between 2 – 20 employees in their latest annual reports, but a minority of the companies had activities in other sectors, hence total reported employee numbers reached 60-80 staff in some cases, but not all of these staff were focused on digital health activities. In the larger SMEs, and probably from ~10-15 employees upwards, more formalised management and business development structures would be expected to be in place, which would be advantageous when dealing with the demands of the digital health sector.

The selection tried to capture a range of digital health sub-categories e.g. businesses operating in both NHS and private markets, businesses addressing health and social care needs, personal health apps, medical device regulated products, etc.

Most of the companies were already developing products for, or selling into UK digital health markets, a minority were active in developing or selling to international customers.

Reported net asset value and employee numbers were checked to ensure SME qualification, along with a review of primary and other trading locations to broadly confirm the operational trading location was in Scotland.

A retrospective assessment of this particular selection of companies is discussed in more detail in the Observations section.

Methodology

The methodology of the interview was a scheduled online Microsoft Teams call with a founding director or senior executive management, outlining the eight questions detailed below, prefaced by an explanation of the purpose of the survey, why it was being carried out and who was carrying out the survey.

As a common starting point, a statement was made at the start of each conversation to set direction and to avoid spending limited time on already widely recognised additional challenges for those operating in the digital health space. This statement was that the digital health market is recognised as being challenging relative to other markets due to range of factors that includes:

> "*navigating multi-agency health systems, comprehensive and extended testing for evidence base, complex existing operating / adoption pathways, system interoperability requirements, regulated procurement procedures, health economics / innovation value studies; medical device / data security / data governance legislation, etc.*"

The eight questions were grouped as follows, along with a final "any other comments" opportunity.

Perceived and Actual Barriers

- When considering your initial entry into the digital healthcare market, were there any perceived challenges over and above the examples set out that you anticipated that did not subsequently materialise?
- What would you consider as the most significant barriers that were encountered during entry into the digital health market?

Support and Other Factors

- What additional support do you think would have been beneficial to your venture during the early stage of entry into the digital health market to help overcome barriers to entry?
- Can you identify any support or other factors that materially contributed or detracted from the progress of your venture to date?

Future Barriers and Support

- Looking forward what do you anticipate will be the biggest barriers to the growth and future ambitions of your SME in the digital health market?
- What support do you think would help overcome these barriers?

Competitors and Other Markets

- Are you aware of any support programmes or other digital health initiatives outside of Scotland that you think should be considered for provision within Scotland?
- Regarding competitors who are not based in Scotland, can you outline any advantages that you consider they may have in growing their business in their home market relative to your business growth plans in Scotland?

Interviewees were made aware that it was intended that the findings of the report were to be made public. On that basis, to ensure an open dialogue, it was decided to not record any of the interviews other than via notes, and to not attribute any specific comments in the report to any identifiable participant. Given the small number of interviewees, numerical analysis of responses was not thought appropriate.

The Discussion of the SME Responses, and Conclusion and Recommendations have sought to identify common themes and perspectives with conclusions and recommendations based on these.

SME Responses - Perceived and actual barriers

Companies were initially asked about barriers they had perceived prior to their entry to the digital healthcare space. All SMEs recognised and agreed with the statement that had been made at the start of the interview regarding the additional digital health barriers and then highlighted, to varying degrees, that the barriers they had encountered were significantly worse than they had feared, especially in the circumstances where companies were required to engage with the NHS and wider care systems.

- It was widely considered extremely challenging to secure initial project traction and then to maintain progress, particularly for SMEs who may not have the resources available to e.g. manage extended delays in decision making, funding or next stage development.

- There were concerns expressed that the NHS messaging around being open for innovation was superficial and that the reality was that the NHS was a very closed environment and inaccessible to SMEs.

- For many companies, barriers such as health economics, procurement etc. were not at the forefront as there were numerous other barriers to get through before that point was reached.

- Even those with experience and understanding of the NHS and its complexity still struggled with the intensity of the challenges they experienced.

- Comparisons were made to other industries, with concerns expressed regarding out of date technologies in use in the social and health sector, and the contrast between state of the art, high-tech treatment technology, and out of date or disjointed support systems.

- In some cases, the view was that the technology gap between the SME supplier and the prospective health and care customer was wider than anticipated and was a significant challenge for SMEs looking to sell state-of-the-art innovative technologies and systems.

- The pace of decision making, and the complexity of the health and care sector were often cited as barriers for SMEs. Multi month timescales for decisions, payment issues to be resolved or research funding to be issued were all listed as potential survival issues for small SMEs.

- There was concern that in some cases the agenda was not about bringing in innovation from external sources, but was instead harvesting innovative ideas and products from SMEs as a data gathering exercise at a research stage, which might then end up as part of an in-house development project.

- The difficulties for the companies in securing sales in their home market, particularly if this was to the NHS given its international standing, then put these companies at a disadvantage for entry into export healthcare markets, as a key question and expectation would be around traction in their home market. This contrasted with incoming companies who, having secured customers in their domestic markets, would then have an advantage.

- Difficulty in accessing data and resources needed to prove outcomes and benefits of their product were a challenge for SMEs. A key part of this was identifying and accessing the relevant clinicians or operational staff, which then also linked into helping the product take root operationally. It was acknowledged that this staff access was hampered due to a lack of time and resource to engage effectively with SMEs.

- Interviewees noted delays between policy decisions becoming practice, linking this with the health and care sector capability and rate of adoption of digital innovation as a factor.

- It was recognised that the eHealth teams within the NHS and care providers faced issues of being under-resourced and struggling to give digital innovation sufficient attention, paraphrased by one as "innovation being the easy bit, staffing the pathways with people that can manage projects or innovation the limitation; and without people in those organisations with the right abilities, you hit a problem".

- A further issue cited was grant-based projects alignment to SME timescales, and then lacking a clear or formal route to adoption or guarantee that the innovation would ever find its way into the system to benefit patients. For the organisations involved, this made it difficult to put forward a financial case for investment.

- A final challenge for SMEs was tracking and navigating the increasing range of agencies involved in the sector and the related support programmes.

SME Responses - Support and other factors

The most successful companies appeared to be the ones that either had other business activities; were selling the same products to non-digital health markets; were already insiders in the NHS and benefitted from extensive support or had bypassed the Scottish health and care sector as their primary market and identified alternative points of support and entry to the health and care sector. These companies acknowledged that for other SMEs it would be extremely difficult to build their business and enter the sector if they did not make use of the available support.

- One interviewee observed that there had been a lack of vision and ambition when accessing support agencies in Scotland. This contrasted with subsequent offers to access support in other countries where they were presented with a very different view of what was possible and what could be achieved.

- There was an observation that the support that had been given needed to be deeper, long term support, with follow up and help navigating a complex environment – a more holistic view of support. This also extended to improving support for international sales.

- Some businesses had accessed multiple support programs, including programmes outwith Scotland, benefiting from the additional support and networking opportunities.

- Funding availability was commonly highlighted, both in a positive sense as a key support factor where it had been secured, and as a negative where lack of access would be critical.

- UK investor caution about investing in early-stage innovation companies where the NHS was a potential key customer was an issue due to perceptions regarding innovation adoption timescales and market visibility.

- Specifically accessing non-UK focused support and funding at an early stage was identified as a positive success factor.

- The limited number of commercial funding sources in Scotland was noted, with conflicts of interest quickly arising where competitor companies were funded, requiring companies to look elsewhere for investment.

- There was a concern re multi-year grant funding projects becoming overly focused on delivering the grant project plan to pre-agreed milestones set several years back against a particular set of outcomes, rather than making relevant progress.

- Wider support for SMEs was identified as an issue, with medical staff perceived as being guarded about supporting companies or products, whereas in other countries there seemed to be greater willingness to champion their own companies.

- Not focusing solely on the NHS was a success factor, which potentially then linked to less interest in specific NHS focused support programmes. This extended into the view that there was a limit to how much support programmes could achieve as the major issues lay elsewhere.

- A potential difference between domestic and overseas health providers regarding access to cost saving information was noted, with overseas providers possibly sharing this information more readily.

SME Responses – Future Barriers and Support

The most frequently mentioned barrier to progress was seen to be the NHS and their willingness to engage with SMEs and need for the NHS to improve as a customer when interacting with SMEs.

- Accessing non-Scottish markets was identified as key given the limited domestic market. Support to identify and develop alternative routes into health and care revenue would be useful for many businesses.

- Most companies spoken to were either moving into international markets or looking to move into them as the UK health and care system was too challenging and limiting to work with. For non-treatment related innovations there was also a view that overly focusing on the NHS might limit wider applicability, as the product or service may not translate from one country or healthcare system into another.

- The imperative that every business in the digital health sector should be viewed as a global business was mentioned a number of times, hence any support programme that was overly focused on helping secure opportunities within the Scottish health and care market would be less attractive given the relative scale of that market.

- Securing overseas sales also involved considerable risk and financial outlay due to market complexities, e.g. pilot programmes could be several times larger than the equivalent in the UK, which was a significant step-up if the SME was underdeveloped due to the local market limitations.

- A positive arising from the Covid crisis had been an accelerated understanding of the value of data exchange and remote monitoring, which is a key attribute of digital health. As a result, projects had gone from clinical pilot to national adoption through access to key decision makers, who now understood key elements of the digital health agenda.

- Concerns were expressed about the benefits arising from the Covid crisis being rolled back when temporarily deployed systems were re-procured and the SMEs disadvantaged despite having provided the innovation when needed.

- A perceived lack of resource bandwidth within the NHS and care providers regarding software and the digital health space was highlighted, and that this may extend to procurement. This lack of resource also linked into operational staff and departments being more concerned with the day-to-day, therefore making it difficult for companies to access people who understand the value of digital health innovation.

- Again, access to appropriate funding and SME staff with the skills and knowledge to navigate health and care systems and cultures was mentioned as a key barrier.

- A need for wider horizon scanning within health and care sectors was highlighted, particularly where new digital innovations did not necessarily fit solely into existing operational silos. This was particularly a challenge with some larger cross agency health and care projects.

- The economic opportunity to pro-actively use health spending as a wider economic catalyst was noted, where the NHS could focus on being the best and most supportive customer it could for SMEs and organisations developing and delivering innovation.

- Support for accreditation was suggested, particularly with respect to software medical device regulations as a key emerging area which also has a potential scarcity and significant expense to access resource and expertise.

- A minimum turnover level threshold for access to certain existing support programmes was noted by one as being a challenge for digital health SMEs given adoption timescales and limited initial funding if working through a pilot project approach.

- The issue of the NHS not wanting companies to grow and become dominant in the market was raised, and whether this approach, when applied too early, was holding back SME development, e.g. overly commercialising small markets with multiple, sub-viable competitors.

- Internal customer competition and potential IP leakage, and conflicts of interest were mentioned as a concern where internal development projects were also a possible development route for the customer.

- An ongoing focus on treatments was noted as opposed to considering wider societal solutions e.g. maintaining people at home for as long as possible.

SME Responses - Competitors and Other Markets

The innovation culture in other countries and their attitudes and support of small companies looking to enter the public sector was highlighted, with Estonia being mentioned several times. This was linked to the point around the public sector "needing to learn to be a better customer"; Estonia was highlighted as a successful example of this, where it had identified development of the SME base as a key issue.

Access to organised multi-nation international development programmes was noted as being important to accessing diversified, larger markets given the size of Scottish or UK markets in absolute terms.

- The US was highlighted multiple times as an example of a more commercial healthcare environment, which was more conducive to SMEs entering the market and becoming embedded.

- One interviewee suggested any sponsorship or financial support from UK support organisations should include a local use case as an outcome, which would then support access to international markets by ensuring the SME had a domestic reference customer.

- There was evidence of valuable financial incentives on offer to relocate to other countries such as Israel / Switzerland / Eire / US; including accommodation, access to staff and technologies, and reduced taxes.

- Good access to NHS X, NHS England Academic Health Science Networks etc. was valuable as NHS England was a further challenge to navigate.

- Other countries that were mentioned included Finland, Korea, and France, where state support for digital health companies appeared more comprehensive.

- There was a feeling that in some cases it was more difficult to enter the local (UK) market as an indigenous company despite having equivalent technology to overseas competitors.

Observations

The strength and coherence of views expressed, across a wide range of companies at different stages of development, was such that a further and fuller investigation of the sector challenges and barriers should be carried out to cross check the findings.

Given the relatively small sample size from the longlist, which also then tried to ensure a range of views across a variety of SME development stages and digital sub-sectors, there is the possibility that the cohort of companies was not a truly representative sample of experiences either at the shortlist level or, potentially, from the longlist.

One possibility is that in selecting a range of companies for interview covering devices, personal health apps, decision support software and enterprise / infrastructure software, the findings reflect the fact that it is more challenging for SMEs to secure engagement with the latter categories, as existing digital health support programmes and innovation expectations are more focused on SMEs with innovative devices or personal health apps.

A best practice feature of the digital health support programmes identified in the findings of WP1 is that the programmes focus extensively on early identification, qualification, and triage of programme appropriate companies. It may be that some of the companies selected were in the process of being, or had already effectively been, triaged from the system, and hence this would generally give rise to negative feedback. Another factor might be that one would expect to find fewer, quite specific demand led innovation requirements from digital health and care sector customers (technology pull), versus a much larger number of supply side innovations being presented for consideration (technology push). This inevitable mismatch of "pull" and "push", current-needs customer focus versus future "interesting" innovation is a constant challenge for innovation managers to balance.

A larger survey would hopefully generate a wider range of views, allowing for a clearer stratification and insight into the companies within the digital health and care sector, between those that match the criteria of the existing support structures and those that don't, hence who may require alternative support strategies. Even allowing for this, the recurring themes mentioned multiple times during the interviews point to major issues for SMEs operating in the digital health and care sector. These challenges and barriers are over and above the normal barriers and challenges, AND are in addition to the challenges and barriers identified at the start of each interview.

For reference, each interview started with the statement that, in addition to the usual challenges and barriers that faced any SME, SMEs operating in the digital health sector faced additional challenges that: -

> "*can include navigating multi-agency health systems, comprehensive and extended testing for evidence base, complex existing operating / adoption pathways, system interoperability requirements, regulated procurement procedures, health economics / innovation value studies; medical device / data security / data governance legislation, etc.*"

All the companies interviewed agreed with this statement as an opening position summarising the additional digital health sector challenges.

The interviews point to a complex and, at times, damaging third set of challenges and barriers facing digital health SMEs. Whilst that may appear to be a strong statement, the interviewees did have a wide range of business experience, often at senior levels in other businesses, or successfully running other parts of their business in non-digital health sectors. The comments were not made lightly, and the themes recurred across the interviews.

There is also a recognition that needs to be made in the interpretation of interview comments, that there are at least two sides to a business relationship. In the case of SMEs dealing with the NHS, there may just actually be a fundamental insurmountable mismatch in scale between the prospective customer's needs in any one area and the prospective supplier capability and aspirations. This has been considered in the discussion.

Having extensive experience working with both health and social care organisations and with SMEs, we are well rehearsed in the counter argument to many of the issues raised or understand the behaviour patterns that give rise to the issues. The sample size was small, and the data is inevitably anecdotal, however as noted at the start of the section, the strength and coherence of the views expressed was notable and warrants further investigation.

A Third Set of Challenges and Barriers

We have made an initial attempt to group the views into a Third Set of Challenges and Barriers for Digital Health SMEs, under the headings of Expectation Management, Timescales, Funding and Good Customers.

Expectation Management - Establishing Trust and Credibility

SMEs entering the digital health market must completely reset any previous assumptions or experience in other sectors regarding their ability to establish trust and credibility.

Unless they have come from within the system, it appears to take longer to establish trust and credibility than in other markets. A further issue when dealing with the UK health and care systems are underlying concerns regarding privatisation, commercialisation and heightened data governance and security issues that can impede relationships. While this approach may appear reasonable from a customer perspective, given what is at stake, this holds back innovative SMEs that are trying to establish themselves and grow.

For some SMEs the Covid crisis has been of benefit, as digital health applications offered the possibility of information exchange without direct contact. Some SMEs have seen more rapid progress to deployment at scale than would have been expected without the crisis. For others, the crisis has held

up access to vital business development opportunities, but in essence the immediate needs of the crisis set aside wider reservations and allowed the SMEs to do what they are best placed to do; innovate at speed. There are however concerns that post-Covid these contracts will once more enter tendering cycles, putting SMEs at a disadvantage to financially stronger competitors.

Timescales

Closely related to the first point are the extended timescales for digital health projects. Whether multi-agency projects involving complex data hand-offs, new clinical pathways, regulated devices, or serial request for pilot projects, the public sector health and social care system operates on different timescales to SMEs. In this regard, there may just be a fundamental mismatch unless very significant changes were made to the system.

The optimal position appears to be that in the digital health market, from a business survival perspective, the SME should always have another income source. Whether this is operating in alternative business sectors or different digital healthcare markets, or having completely unrelated income, the outcome is the same. It enables the SME to survive and brings longevity, which increases the probability of the innovation and market opportunity eventually aligning. (A possible logical outcome of this challenge is that some SMEs move to a strategy of creating and running multiple innovation projects, in effect adopting a portfolio approach to innovation success on the basis that the timeline and outcome of any single project is too uncertain, for many reasons, to support the SME.)

Quoted examples of three-month timescales between meetings are manageable for established corporates and publicly funded bodies, but if everybody attending the meeting was also not going to receive revenue and a salary in the interim, as may be the case with an SME, then the focus on more immediate action would change. Timescales also link to the budget cycles and funding structures of public health and social care systems, and the challenges of changing them. Innovation involving pilot projects that did not have any budget allocation to deploy the innovation immediately post-pilot were viewed very negatively.

Even for well-funded digital health technologies that were being more widely deployed, the certainty of securing long-term, multi-year contracts appears to be a challenge. This may be a feature of the embryonic and evolving nature of digital health solutions and a lack of willingness to fully commit to new technologies, but there does appear to be a precariousness to the funding that then has a knock-on effect to the growth, investment prospects and sustainability of SMEs.

Funding

While there are sources of start-up support funding and small-scale pilot funding through SBRI / UKTI, etc., and other targeted funding calls and competitions, the niche and specialist nature of the funding and limited number of commercial funding sources in Scotland is a challenge. SMEs can quickly find that the sector appropriate funders have already backed competing businesses and have conflict of interest or portfolio balance issues.

Another funding challenge is that many funders are cautious about digital health projects due to the extended timescales and uncertain product adoption outcomes at sustainable and profitable scale, even for later stage products.

These funding constraints then drive businesses to look to overseas markets if they are to achieve scale, however this is a significant challenge as often the first question asked of these companies is whether they have sold in their home market.

Alongside this, it is not clear whether the volume of pilot scale funding is appropriately matched to the availability of next stage funding. This applies to both funding for the SME's internal growth requirements and the funding for the customer's innovation deployment. All parts need to be synchronised at a sufficient level to be able to ensure that (i) viable projects develop and are not left as unfunded, dead-end projects and (ii) that there is the prospect that contracts are awarded with sufficient value to attract commercial investment into the SMEs.

Good Customers

The "good customer" point was raised by several interviewees, being mentioned in tandem with Estonia as an example of a country that had grown a successful digital health ecosystem. Part of that success was the principle that the public sector needed to learn to act as a good customer.

This appears to be something that has been recognised more widely in the UK. We have not researched the topic exhaustively, but discussions with health sector procurement specialists as part of the baseline assessment work highlighted strategies that are being developed, or are already underway, that appear to encompass some key principles.

From an SME perspective, a good customer will be one that assesses a new product in a timely manner, understands SMEs, is willing to pay for the innovation phase and will work together with the SME to deploy the innovation into their business, pays a fair price for the product, moves to deployment at an economically viable scale for the SME, is a repeat or long term customer, and is perhaps willing to act from time to time as a reference customer for the next sale that the SME is trying to make.

Examples of a "bad customer" can illustrate this issue. Small pilot trials that are more to the customer's benefit than any real intent to buy, unnecessary pilots of products already proven in other areas, protracted delay or lack of connectivity between pilot and commercial contract phases, forced retendering between innovation proof point and adoption, latent conflicts of interest between potential internal delivery options and external innovation bidders, and lack of understanding as to what constitutes a commercially viable long term value commitment to the innovation and the SME.

Conclusion and Recommendation

All interviewees talked about significant challenges, over and above the normal challenges and barriers to any SME and the additional widely identified barriers for digital health sector SMEs. Some interviewees alluded to actively avoiding certain markets, and investors doing likewise.

The first conclusion and recommendation is that more work should be carried out to understand the issues for this sector. If this has been identified as a key growth sector then, while the situation may have changed from when this cohort of companies started trading, the message from this survey was essentially unanimous.

If the intent is still to proceed with further support programmes, despite the frank advice of some interviewees of not encouraging false hope though inappropriately pitched digital health innovation programmes targeting SMEs, then the support should be an "unvarnished" entry level programme. It should, in addition to providing a full understanding of the previously mentioned digital health additional challenges and barriers, upskill participants in topics such as: -

- securing evidence of benefit and health economics studies;
- health and social care organisation structures across the UK;
- procurement and commissioning;
- data security and data governance requirements;
- software medical device regulations

and then include: -

- a focus on the extreme challenges of the sector;
- early triage by appropriate sector experts to calibrate expectations;
- strategies for generating alternative income;
- recalibration of assumptions regarding investment funding;
- accessing digital health markets outwith Scotland,
- support to secure reference customers.

Appendix A – Long list of exemplar programmes

The following exemplar programmes were considered for inclusion in the report but where excluded as there were other programmes that more closely aligned with the criteria agreed with Scottish Enterprise (UK based programmes are in **bold**):

Long List (did not meet criteria)	Short List (did not meet criteria)	Final List
1. **The University of Edinburgh** 2. **Medovate, Cambridge** 3. **UCL Institute of Healthcare Engineering** 4. National Institute of Biological Sciences, Beijing 5. The Israel Innovation Authority 6. Danish Healthtech 7. Copenhagen Healthtech Cluster 8. UnitedHealthcare Accelerator 9. Massachusetts General Hospital Center for Innovation in Digital HealthCare 10. Indian Institute of Technology Delhi 11. The Digital Medicine Society (DiMe)	1. **Medtech Foundation** 2. **Innovation Exchange** 3. **Queens University Belfast** 4. **Biocity Nottingham** 5. Cluster Saude de Galicia 6. EIT-Bridgehead 7. Karolinska Institute 8. Enterprise Ireland 9. Singapore Centre for Health Innovation 10. DigitalHealth.Berlin	1. **Digital.Health London** 2. **Wayra Health Hub 2020** 3. **Life Sciences Hub Wales** 4. **Health Innovation Manchester** 5. **National Innovation Accelerator** 6. Assistance Publique - Hôpitaux de Paris (AP-HP) 7. Alsace Biovalley 8. Estonian HealthTech Cluster 9. Singapore National Health Innovation Centre

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