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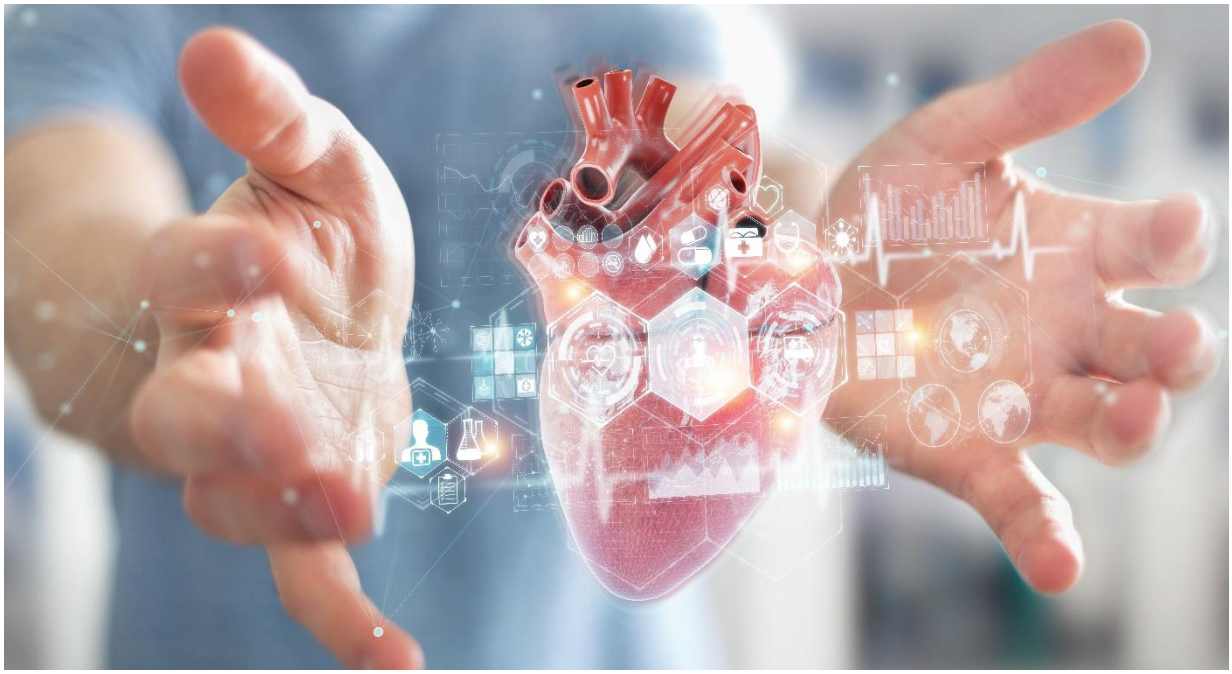
Health Enterprise East

INNOVATION IN CARDIOVASCULAR DISEASE

TRENDS, INSIGHTS & OPPORTUNITIES

7th July 2021



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HEALTH ENTERPRISE EAST LTD.

Medtech Navigator

The Medtech Navigator, part-funded by the European Regional Development Fund (ERDF), is a three-year programme, delivered by Health Enterprise East Ltd., to facilitate knowledge exchange between the medtech industry, many of whom are small and medium sized enterprises (SMEs), the NHS, and academia. The programme seeks to enable companies to identify potential market opportunities in a variety of specific disease areas and apply for Innovation Grant funding through the programme, thereby engaging SMEs in new R&D projects that are both customer-focussed and collaborative in nature. This will allow the creation of partnerships between clinicians, academics and industry to develop novel medical technologies which will improve healthcare and quality of life for patients and the healthcare market of the future.

Health Enterprise East Ltd.

At Health Enterprise East believe in improving healthcare through technology and innovation.

We work with the NHS, medical technology industry and government organisations to help turn innovative ideas into products and services that will benefit patients.

Our experienced team offers clients a diverse range of business and innovation management services. Our strengths include IP management, technology commercialisation, health economics and strategic market access advice.

Based in Cambridge, we work with over 25 NHS organisations nationally and medtech companies globally. Our aim is to help our clients address the challenges faced along the product development pathway, connecting them with relevant healthcare experts and funding opportunities.

Report Summary

This report contains information relevant to those developing innovations in cardiovascular disease. An assessment of the industry landscape is given by analysing the market size and an overview of the larger companies active in the market is provided. We take a closer look at what UK based medtech companies are developing in the cardiovascular disease area with a particular focus on the needs of the NHS and how these needs might be addressed. We analyse the innovations that have been funded by UK based funding bodies such as Innovate UK, SBRI and NIHR i4i. Finally, we review the patent landscape and summarise what the top 5 companies are in each area of interest.

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1. Background

When it comes to ailments and afflictions with an impact on the heart, we place these under categories known as heart disease, or cardiovascular disease (CVD). Some extremely debilitating conditions can arise from CVD such as myocardial infarction (heart attacks), strokes, coronary artery disease, arrhythmias, ischaemic heart disease, and so forth.

One of the leading causes of mortality in England, and certainly the world, stems from CVD – responsible for close to 25% of all mortalities in 2019 throughout the UK, and in countries such as the United States it is estimated that CVD or stroke is prevalent in more than 85 million Americans. What's more, comorbidities (e.g. diabetes, pain, irregular heart rhythm, hypertension, dementia, etc.) have been shown to be disproportionately prevalent in the more deprived and poorer socioeconomic areas across England. With CVD prevalence expected to grow due to an aging population so too will the associated costs and economic burden that the healthcare and social care systems will have to shoulder, a heavy toll to consider going forwards seeing as recent data estimate CVD expenditure accounting for more than 20% of all NHS costs (> £15 billion) annually. As a result, the global CVD medical device market is expected to rise to a valuation of more than £50 billion by 2027.

MedTech companies and innovators are now laying the groundwork to position themselves in tackling some of the growing concerns taking place in CVD across the healthcare landscape. This means a total shift in perspective as to the protocols, tools, devices, and technologies required from enterprises to promote patient well-being, payer and provider engagement, diagnostic and surgical efficiency, and every other step within the CVD management pathway.

Unmet Needs

The CVD prevention optimal value pathway, published by the NHS RightCare programme [1], has identified six high risk CVD conditions demonstrating notable underdiagnosis and poor clinical management in spite of a host of currently in-use interventions. They are as follows:

- High blood pressure
- Atrial Fibrillation (AF)
- Familial Hypercholesterolemia (FH)
- Non-diabetic hyperglycaemia
- Diabetes (Type 1 and 2)
- Chronic Kidney Disease (CKD)

1.1 CVD's Place Within the NHS Long Term Plan

The NHS's answer in establishing an ever shifting and iteratively progressive healthcare system built on the foundation of long-term (i.e. next decade) results is set forth by the NHS Long Term Plan – a collaborative melding of ideas, feedback, and milestones grounded in reality put forth by national experts, patient cohorts, and frontline staff.

Using a recent Global Burden of Disease study, the NHS has placed CVD as a priority for focussed clinical improvement; even after successfully halving the death rates from CVD since 1990, the NHS has made clear that it is the single most pertinent area in which lives can be saved over the next decade. Highlights for the plan of action are found under Chapter Three of the NHS Long Term Plan with specific emphases placed on more robust protocols surrounding prevention, early detection, treatment, uptick in rehabilitation services, and promptness in first responder action [2]. Specifically, the NHS has laid out:

- **Fostering lifestyle changes and compliance** through public health and NHS channels for smoking cessation, weight loss, responsible alcohol consumption and food reformulation.
- **Earlier detection and treatment for the six identified high-risk conditions.** By comparison, the UK falls behind other healthcare systems in ensuring that the general population is in the habit of knowing their ABC (AF, Blood pressure, and Cholesterol) levels. The NHS proposes that tackling this problem starts by increased implementation of digital technologies, and forming closer connections with the voluntary sector, community pharmacists, public sector, NHS staff, and employers.
- **Increased rollout and throughput for programmes such as NHS Health Check and NHS Genomics.** FH is a prime opportunity for improved prognosis with this measure as it is believed that a paltry 7% of FH sufferers in the UK have been identified – the NHS Genomics programme, in combination with increased yield to genetic testing, is

looked at as a key component for more than tripling the levels of identification over the next five years.

- **Proactive support within primary care from specialists and multi-disciplinary teams.** This measure has been put into place after identifying that, in the UK, approximately 4 out of 5 patients with heart failure are diagnosed in secondary care even though 40% of said patients demonstrated symptoms that could have been identified earlier. Proposals to rectify this include increased access to personalised planning, specialist nurses, and echocardiography scans in primary care.
- **Developing a robust network of defibrillators and community first responders for prompt response to cardiac arrests occurring outside hospitals.** The NHS will consolidate data from the British Heart Foundation's Outcomes Registry so that survival rates can be monitored, and community aid can be directed to areas of need. By 2028, the NHS estimates that successful rollout of this initiative will be responsible for saving up to 4,000 lives/year.
- **Ramping up patient follow though/uptake rates for cardiac rehabilitation.** Only a little over half of the 121,500 eligible patients partake in offers for cardiac rehabilitation. This is an area for active improvement as NICE, as part of their NG185 guidance, have identified cardiac rehabilitation to be a key component in increasing markers for quality of life and reductions in hospital readmissions for Acute coronary syndromes [3]. It is estimated that this increase in scalability will remove up to 50,000 acute admissions and 23,000 early deaths over the next decade.

1.2 Setting up the NHS Long Term Plan for Success

Fruitful outcomes for CVD patients from the planned points of action outlined in the CVD Prevention programme are contingent on capitalising on partnerships (via several organisations, groups, and associations) with the NHS [4]. Key partnerships in the eyes of the NHS for a successful Long Term Plan include:

- British Heart Foundation (BHF)
- Stroke Association
- Academic Health Science Networks (AHSNs)
- Public Health England
- Voluntary sector associations

A great example of how the "whole systems approach" in tackling high-risk CVD conditions is working comes by way of BHF support after just one year into the 10-year NHS Long Term Plan. The initiation of a systematic cascade testing programme for FH has already allowed BHF funded nurses to identify more than 1,000 people with FH [5] – paving the way towards an expected 25% detection rate (currently at 5%) of FH by 2024 [6]. Adding to this, a published paper in the European Heart Journal, commissioned by BHF, reported that the incremental

cost effectiveness ratio (ICER) for every relative of those with FH was estimated to be £5,806 – far below the threshold of £20,000 - £30,000 set out by NICE [7].

Achieving the national ambitions that have been laid out as part of the Cardiovascular Disease Prevention System Leadership Forum (CVDSLF) [8] for the identified high-risk CVD conditions (Table 1) means deemphasising the burden placed on primary care. Instead, leveraging efforts from all the key partnerships previously discussed is pivotal in pushing down discrepancy in CVD morbidity and mortality between areas of high and low indices of deprivation. Bringing these levels more in line with one another is important as, from a PHE inquiry, approximately 40% of preventable CVD deaths are relegated to the most deprived 1/3 in England [8].

CVD 10 YEAR AMBITIONS FOR ENGLAND (NHS LONG TERM PLAN)

Objective	Atrial Fibrillation (by 2029)	High Blood Pressure (by 2029)	Familial Hypercholesterolaemia (by 2024)
Expected Sufferers Diagnosed	85%	80%	25%
Patient Population Provided Treatment	90%	80%	25%

Table 1 – Diagnosis and treatment targets set out as part of the NHS Long Term plan through until 2029. Data adapted from PHE (Health Matters) CVDSLF, accessed 27th May 2021 [8]

2. CVD – The Addressable Patient Population

2.1 United Kingdom

As of January 2021, is it estimated that close to 6.4 million people residing within England are living with CVD [9]. In addition, a little over a quarter of all mortalities in 2019 within the UK were attributed to CVD (Figure 1), second only to cancer. Data pulled from statistical compendiums released by the BHF in partnership with Imperial College Health Partners (ICHP) allow for further granularization into the types of CVD contributing to yearly mortality rates, as shown in Figure 2 – we can see that coronary heart disease (CHD) and stroke when combined make up close to two-thirds of all CVD related mortalities, with a near 70% higher mortality rate in males than females for CHD. Figure 3 provides a full breakdown regarding the estimated prevalence of the six target risk conditions in CVD across the UK.

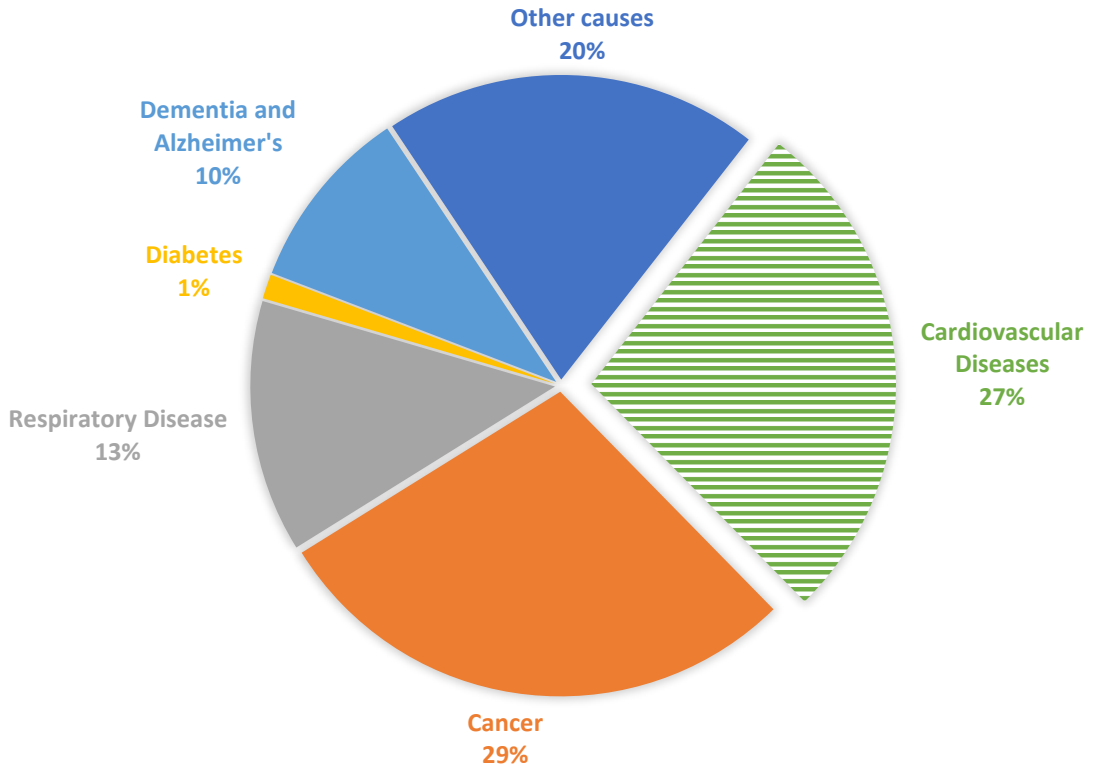

Figure 1 – Distribution of mortality by cause within the UK for the year of 2019 [10]

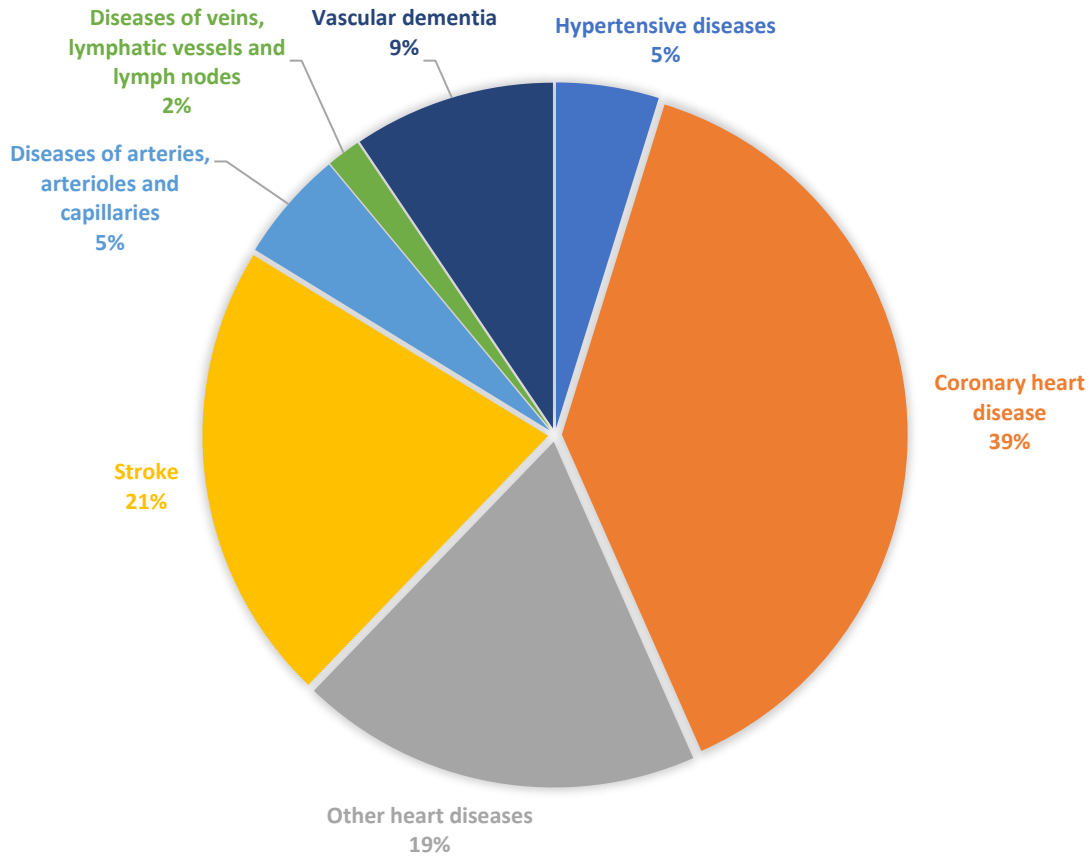

Figure 2 – Breakdown by subdivision of CVD related mortalities within the UK for the year of 2019 [10]

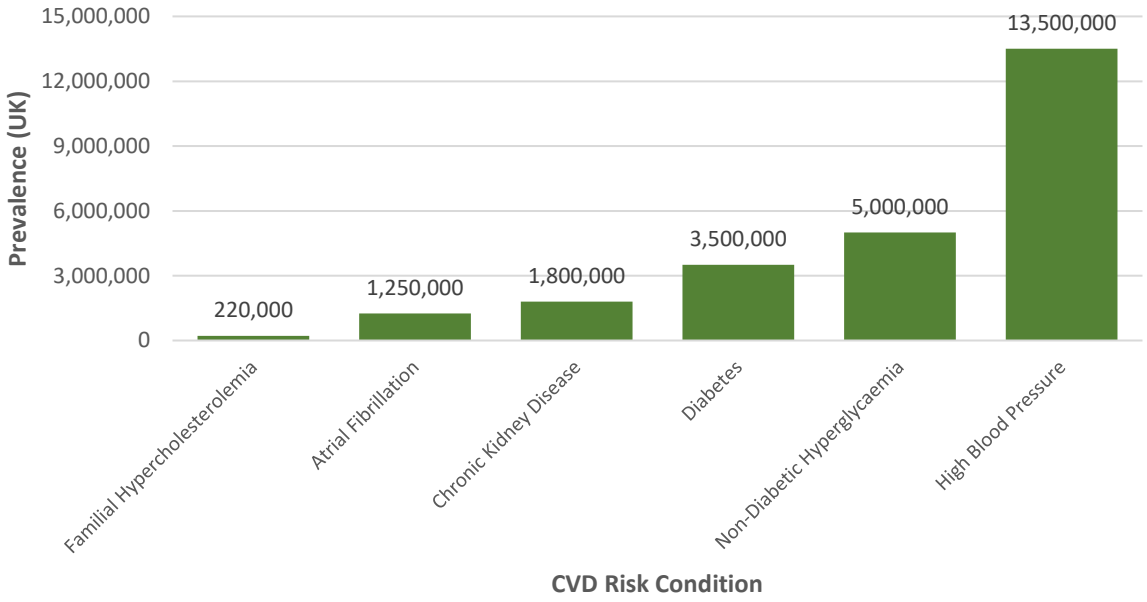

Figure 3 – Prevalence within the UK of NHS' six identified CVD risk conditions [11], [9], [12], [13], [14]

Three of the major risk factors to stroke, the second leading cause of CVD related mortalities, comes as a result of AF, diabetes, and high blood pressure – three of the six CVD conditions identified by the NHS as having poor clinical management. People with AF in England (~1.25 million) have been shown to be five times more susceptible to suffer from stroke, adults with diabetes (~3.5 million) carry a two-fold risk of being predisposed to stroke, and lastly almost half of all stroke cases are traced back to those diagnosed with high blood pressure – the leading amendable risk factor for CVD [9].

The geographic distribution of the prevalence in the UK is important to consider also. Upstream risk factors for CVD (e.g. lack of exercise, obesity, smoking, alcohol consumption, etc.) are known to increase with levels of deprivation in the UK. Correlated with these levels of deprivation are an increased risk for most, if not all, the CVD conditions shown above in Figure 3, and, ultimately, CVD related death. These deprived areas go on to face the brunt of healthcare related costs associated with CVD management, as well as having the highest recorded numbers surrounding CVD related mortalities. To put this juxtaposition in health-related outcomes into perspective, the denizens of West Dunbartonshire (ranked as the having the highest index of multiple deprivation (IMD) in the UK) are almost 2.5x more likely to die as a result of CVD than those in Hart (lowest IMD). **Error! Reference source not found.**, s hown below, provides a visual reference as to the relational impact between IMD and the incidence of CVD related deaths (irrespective of age demographic) broken down by areas of local authority in the UK.

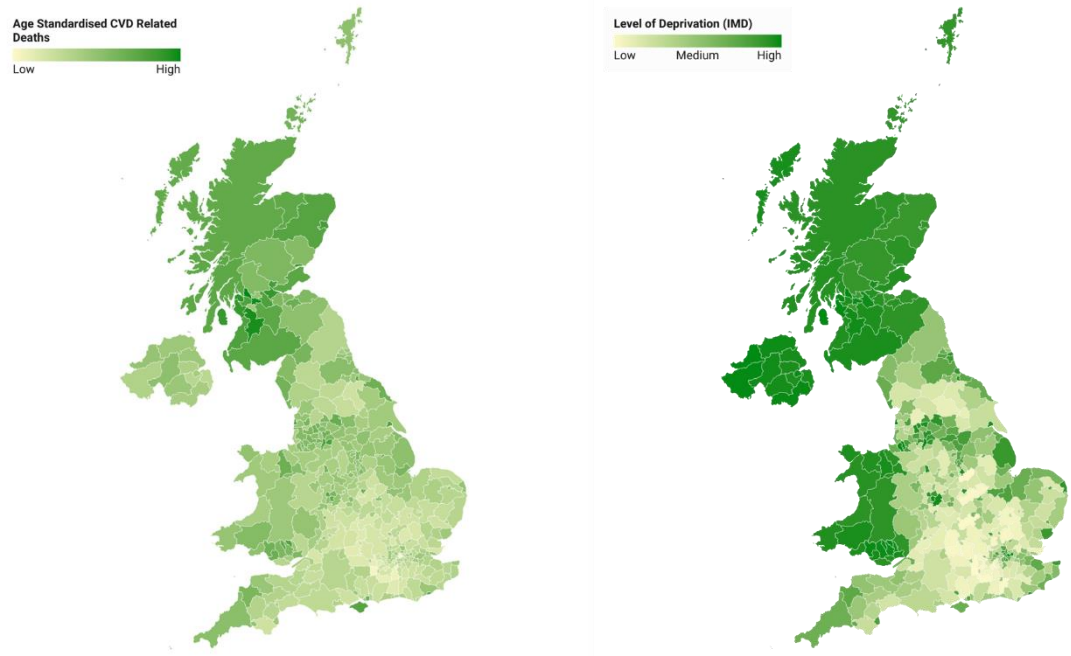

Figure 4 – Age standardised CVD related mortalities (left) and Index of Multiple Deprivation (right) by areas of local authority [15] (Source: Office for National Statistics licensed under the Open Government Licence v.3.0.) (Contains OS data © Crown copyright and database right [2020])

3. Market Size

A study conducted by the European Heart Network reported that the economic impact of CVD on the UK economy in 2015 was near €27 billion, with 46% (€12 billion) being attributed to direct health care costs – more than half of which being attributed to inpatient care. Similarly, from the same report, the annual economic burden of ischemic heart disease (IHD) and cerebrovascular diseases on the NHS are estimated to be €2.2 billion and €2.7 billion, respectively [16].

Globally, monitoring and diagnostic devices for the management and/or treatment of CVD were valued at approximately US$2.2 billion in 2020. Forecasts over a 7-year period (2020-2027) settle on a 6.1% CAGR, lining the market up to reach a total size of US$3.3 billion in 2027 [17]. However, when accounting for medical devices beyond, while also including, the scope of monitoring and diagnostic devices, the international CVD devices market skyrockets to an estimated valuation of US$45 billion in 2020 with a 6.4% CAGR over the same forecast period, meaning a potential valuation of US$69.5 billion in 2027 [18].

Relating this back to the UK and the six NHS identified high-risk CVD conditions, we can start to build a picture as to the economic burden placed on the healthcare system through mismanaged practices across the care pathway:

- **High Blood Pressure -** £2 billion per year [19]
- **AF -** £1.4 – £2.5 billion per year [20]
- **FH -** £7 million per year [21]
- **Diabetes (Type 1 and 2)** - ~£10 billion per year. ~88% of this cost is associated with Type 2 diabetes. From the total costs, 80% of diabetes spending is put towards complications, as opposed to treatment, with CVD making up the largest percentage of said complications [22] (cost breakdown shown in Figure 5)
- **Non-diabetic hyperglycaemia -** Projected savings of £40 million per year [22]

***CKD** - ~£1.45 billion per year (rising to ~£1.67 billion per year when accounting for social care costs from excess strokes in CKD). Cost breakdown for clinical CVD risk areas shown below in*

- Table 2 [12]

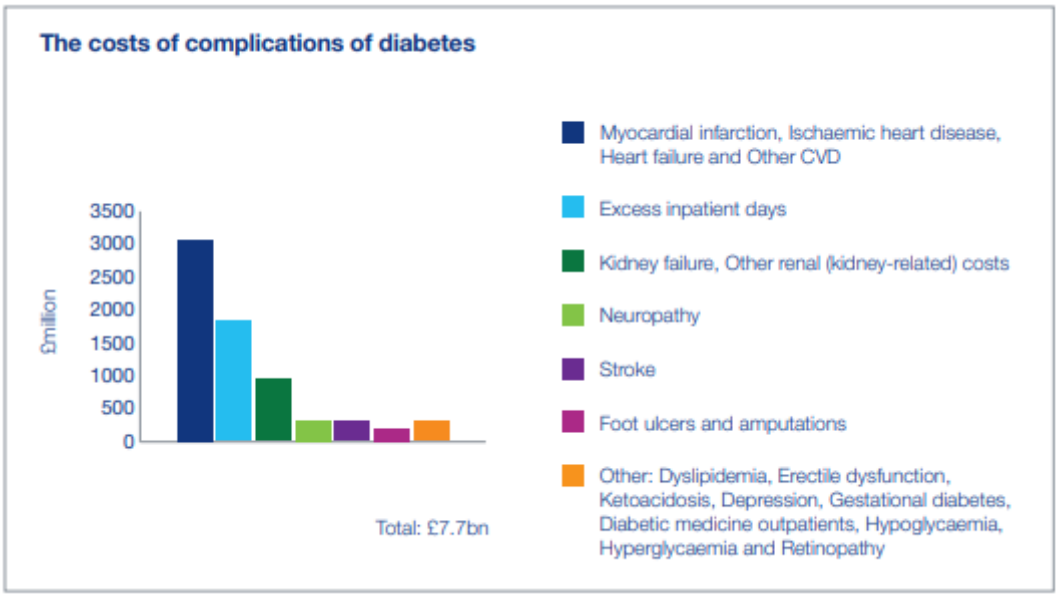

Figure 5 – Cost breakdown of complications (including CVD) associated with diabetes (Source: Diabetes UK – The Cost of Diabetes Report [22])

	Unit Costs	Events	Cost
Stroke	£12,200	6,734	£82,155,382
Myocardial Infarction	£7,734	12,334	£95,391,156
Total	£19,934	19,068	£177,546,538

Table 2 – Associated costs of excess stroke and myocardial infarction resulting from CKD. Expected to be below true estimate as a host of other excess risk CVD conditions, such as heart failure, and ischaemic heart disease, are attributed to CKD patients (Data adapted and sourced from: NHS – Chronic Kidney Disease in England: The Human and Financial Cost [12])

3.1 Medical Devices and CVD

Medical care for patients suffering from CVD relies heavily on cardiology medical devices, and their iterative development and expanding range indications. Examples of said medical devices span the gamut from remote cardiac monitoring, and ECG equipment to catheters, grafts, and cardiac rhythm management devices [18]. As of late, strides in artificial intelligence (AI) are paving the way forward and show huge promise for diagnostic medical devices. A prime example of this comes from GE Healthcare, where they announced on 12th October 2020 U.S. FDA 510k clearance for the Ultra Edition package on their Vivid cardiovascular ultrasound systems that incorporate AI and neural network centred features – expediting clinician workflow in 2D echo imaging [23].

Insights into the global CVD device market have found the COVID-19 pandemic to have a burdensome effect on production in 2020 -- this effect being compounded due to the high volume of elective operation setbacks following the COVID-19 outbreak. What's more, outside of urgent cases, patient cohorts are now being prescribed medicines and lifestyle alterations to stave off clinical procedures in the meantime. This sudden shift in the spotlight and allocated resources in healthcare following the pandemic have caused temporary hitches for prominent market players; for example, Medtronic's earning presentation in Q4 2020 showcased a 32.8% decline in business for products falling under their Cardiac & Vascular business group [24].

Nevertheless, an assorted number of growth factors have been identified through market analysis over the previously mentioned 7-year forecast period. One such key factor is attributed to the increasing economic burden of cardiac deaths accompanying stroke and cardiomyopathy patients. Similarly, CVD remains the frontrunner with respect to prevalence and cause of death, with certain types, such as ischemic heart disease, accounting for 16% of all deaths worldwide. Prevalence rates as omnipresent as these can chart the way towards innovative devices staking their claim in reducing the economic strain on healthcare systems around the world.

Prominent companies operating globally in the CVD device sphere are Medtronic, Abbott, Boston Scientific, Edwards Lifesciences, Johnson & Johnson, Getinge, Terumo, W.L. Gore & Associates, Lepu Medical Technology, Sorin Group, B.Braun, Tegra, Dermax Medical, Newtech Medical Devices, Argon Medical Devices, Eurocor, Gore, Merit Medical Systems, and SynexMed [25].

While countries within the EU zone, particularly Germany, France, Italy, and the UK, make up a sizeable portion of the CVD device market, it is North America, particularly the United States, that has a stronghold on the devices market. Market research conducted over a 2018 – 2026 forecast period identified the root causes behind this being due to aspects such as

higher prevalence of CVD, larger adoption of minimally invasive treatments, rising older population, reimbursements, and a push towards integrating continuous and remote monitoring devices. Nevertheless, across the same forecast period, countries situated within the Asia-Pacific (namely China, Japan, and India) have showcased the highest CAGR in the CVD devices market due to an ever-increasing rate of obesity within the region.

4. Top 10 Companies in CVD by Device Type

4.1 CVD Diagnostic and Monitoring Devices

To contextualise the companies making up the top 10 list below, it's important to clarify the device types that are categorised as diagnostic and monitoring within CVD [18], [26], [27], [17]:

- ECG Systems, e.g. Resting ECG Systems, and Stress ECG Systems
- Event Monitors
- Holter Monitors
- Mobile Cardiac Telemetry (MCT)
- Implantable Loop Recorders
- ECG Management Systems

The consolidated nature of the CVD market means that several key stakeholder businesses dominate the landscape both in terms of innovative products, as well as the services they provide within CVD diagnostics. Factors such as these, as well as market share, product competitive analysis, acquisitional/partnership background, SWOT analysis, and bargaining power and were taken into consideration for the formation of the top 10 list below:

1. GE Healthcare
2. Philips Healthcare
3. Siemens Healthcare
4. Boston Scientific Corporation
5. St. Jude Medical, Inc.
6. BIOTRONIK SE & Co. KG
7. Medtronic PLC
8. Nihon Kohden Corporation
9. Welch Allyn, Inc.
10. Spacelabs Healthcare

4.2 Therapeutic and Surgical Devices

Branching off from the diagnostic side, CVD devices can also be categorised for use within therapeutic and surgical purposes. To help narrow down the scope by which we measure companies' dominance in this category, we must first establish the CVD devices by that are utilised most for these purposes within healthcare [18]:

- Cardiac Assist Devices
- Cardiac Rhythm Management Devices
- Catheter
- Grafts
- Heart Valves
- Stents

With this in mind, a list companies with a strong foothold within this market has been provided below. Several key indicators similar to above were utilised to develop a sense of the competitive landscape, while also taking into consideration recent key developments and project pipelines for innovative products that companies have recently put forth into the market (e.g. Medtronic's FDA approval in January 2020 for its Micra AV pacemaker):

1. Abbott Laboratories
2. Boston Scientific Corporation
3. Edwards Lifesciences
4. Cardinal Health Inc.
5. Medtronic PLC
6. GE Healthcare
7. WL Gore & Associates Inc.
8. BIOTRONIK SE & Co. KG
9. Siemens Healthineers AG
10. Canon Medical Systems Corporation

5. SMEs Addressing Unmet Needs in CVD

5.1 Keeping a Pulse on Digital Innovations

It is natural to assume that the advantages afforded by digital innovations are more heavily weighted towards either the patient or healthcare system; however, from the studies being published, the benefit is more symbiotic than it may appear. Take, for example, the systematic review/meta-analysis conducted by physicians at the Mayo Clinic, with researchers finding pronounced relative and absolute risk reductions (40% and 7.5%, respectively) for patient

cohorts with underlying/early-stage CVD conditions *after* digital health interventions were adopted into their care routine. Falling within the umbrella of these benefits were reductions in all-cause mortality, CVD morbidity, BMI, weight, systolic blood pressure, total and LDL cholesterol, CVD events, and hospitalisations [28].

Elucidating on the reasons behind this, it becomes apparent that digital health innovations help drive down clinical visitations as data can be now effortlessly gathered and streamed through cloud-based means, and the educational materials packaged within these innovations lend themselves to increased patient compliance and engagement with healthier lifestyle activities. From a healthcare provider's perspective, adoption of such digital innovations already, and will only continue to, provide invaluable support in the clinical decision process as large assortments of raw patient data can be processed – producing evidence-based recommendations for treatment. What's more, hospitals looking to capitalise on digital technologies, specifically those focussed on improving CVD outcomes, are finding cost benefits to be made. For instance, a retrospective analysis on an observational study provided data showcasing not only higher diagnostic yields the year following diagnosis with mobile cardiac telemetry (MCT) (61%), as opposed to Holter (24%), and event (23%) devices, but also a 10 – 15 times return on investment (ROI) within the same timeframe when substituting for MCT [29].

85% -- that's the target set out by NHS England for the uptake of cardiac rehabilitation by eligible patients over the coming decade. The reality is that a little less than a half of eligible patients are in attendance of these rehab programmes [30]. As a result, cardiac rehab specialists, academics, industry leaders, and the National Audit of Cardiac Rehabilitation (NACR) have identified that a sharp uptick in the provision of digital services (e.g. apps, web-based programmes, and particularly those with self-monitoring characteristics) to eligible patients are the only way to realistically meet these far off goals, as only a paltry 3–4% increase in cardiac rehab participation had been registered since 2012. Emphasis must be placed on targeting the age brackets demonstrating the highest CVD prevalence (60 – 79 yrs, 69% prevalence; 80+ years, 86% prevalence) as it is observed these are the very demographics with the lowest adoption rates of mHealth (mobile health) technologies (18% and 13%, respectively) [31].

To illustrate as to how digital-centric care, including apps, fit into the patient journey to promote clinically improved outcomes around prevention, diagnosis, treatment, and management of CVD, please reference Table 3 below:

Table 3 – Examples of how and where digitally enabled technology fits within the patient journey for CVD

Patient Pathway					
	Prevention	**Diagnosis**	**Treatment Protocol**	**Provision of Treatment**	**CVD Management**
Digital Innovation Function	Collation of educational content for patient and facilitates community dialogue	Facilitates in provider/HCP's ability to perform accurate diagnoses	Active and dynamic input into potential methods of treatment	Remote patient prompting and administration of treatment	Accessible monitoring of disease and its progression by patient and clinical specialist
Examples	• Smart devices (wearables and non-wearables) • Data assimilation, clinically backed analysis, apps	• Smart devices (wearables and non-wearables) • Data assimilation	• Smart devices (wearables and non-wearables) • Clinically relevant analytics	• Smart devices (wearables and non-wearables)	• Smart devices (wearables and non-wearables) • Data assimilation, clinically backed analysis, apps
Real Use Case	**FibriCheck** An FDA approved app providing insight into heart rhythm irregularity	**Vocal Analysis App** Beyond Verbal, in partnership with the Mayo Clinic, have developed an app that analyses a patient's vocal features for identified vocal markers (13 in total) that demonstrate an increased likelihood of coronary artery disease	**Reveal™ XT (Medtronic)** Insertable Cardiac Monitor (ICM) capable of detecting AF and capturing ECG and diagnostic data to help determine treatment pathway	**Adapta with Cardiac Compass®** Pacemaker capable of adjusting heart rate within clinically defined parameters for each patient. Data is logged and can be evaluated at scheduled patient-physician meetings	**Merlin.net™ Patient Care Network (Abbott)** Cardiac information gathered from implanted devices can be read and sent to a secure network for remote access by physician/clinician. This follow-up system is solely reliant on having an internet and browser

5.2 Healthcare Apps Supporting CVD Management

mHealth isn't going anywhere anytime soon. In fact, the NHS has gone through concerted efforts to promote the use, function, and deployment of healthcare apps that can run on any number of smart devices that the general population commonly use today. So pivotal are these software innovations that the NHS has set out a digital app repository of sorts known as the NHS Apps Library. Within this library are certified digital health tools that pass the NHS' stringent Digital Technology Assessment Criteria (DTAC), allowing all those involved throughout the healthcare provisioning process (staff, patients, citizens, etc.) to be rest-assured that the technology conforms to standardised measures of clinical safety, data protection, technical security, interoperability and usability and accessibility standards [32].

With regards to CVD, the NHS Apps Library currently promotes the use of several distinct digital tools for management of their conditions:

- **ACR Digital Urinalysis** – An app developed with the purpose of ascertaining kidney function and health, of particular importance for those with diabetes and chronic kidney disease. It works by way of evaluating levels of albumin, creatinine, and albumin to creatinine ratio from a user's pee sample.
- **EXi –** Personalised healthcare is widely accepted as the way of ideal management for medical conditions going forwards. EXi moves us one step towards this goal – a bespoke 12-week exercise plan tailored to the information input by the user, stratifying them based on their risk towards developing a range of conditions that fall under CVD (stroke, diabetes, heart disease, etc.).
- **mySugr –** App centred around diabetes to help sufferers streamline what can be an intense condition to track with accuracy. Functions of the app include the mySugr logbook and mySugr insulin calculator, providing the tools necessary for patients to precisely track all important blood sugar, carbohydrate, and HbA1c levels. Consolidation of these parameters are then presented via an in-app dashboard based off user data from the previous 7 – 90 days; reports can be securely forwarded to relevant healthcare professionals involved in a user's diabetes management.

5.3 CVD Products Close to Market

Building a picture of the innovative landscape within CVD for improving patient wellbeing in the UK allows us to see where efforts are being focussed to tackle the leading problems in the NHS. To help guide us through this, we extrapolated information from the Innovation Agency Exchange – a online hub managed by the Innovation Agency where innovators, service users, businesses, and organisations are provided a platform to connect and showcase innovations throughout various development stages (from innovations in development to proven innovations) across several key clinical areas. Totalling up the innovations in CVD, there exist 33 projects – 13 of which are under evaluation for potential adoption, 19 being proven innovations, 1 being clinically evaluated, and 0 innovations in development [33]. We've highlighted the innovations with a strong association to CVD related issues below:

- **INR Self-testing** by **Inhealthcare**
  - **Aim**: Minimise stroke occurrence for warfarin patients and facilitate management for clinical capacity.
  - **Function:** My Inhealthcare app connects via Bluetooth to Roche's CoaguChek INRange device to stream and actively archive patient readings. These readings communicate with decision support software and existing GP systems so that the patients next dose can be calculated and administered in real time.

- **Zio XT** by **iRhythm Technologies UK**

  - **Aim:** Reduce hospital and nurse/clinician visitations and increase patient compliance for continuous ECG monitoring.
  - **Function:** Small form factor ECG monitoring patch, delivered by mail to patient's home, that can be self-administered and worn for up to 14 days. Device is then sent back via mail so that the data can be analysed and formed into a comprehensive report by ECG technicians, from which the patient's relevant clinician will be able to access following upload into a web-based application.

- **geko™** by **Firstkind Ltd**
  - **Aim:** Prevent/reduce occurrence of Venous thromboembolism (VTE)/venous stasis amongst immobile stroke patients as a potential alternative anti-stasis intervention for patient cohorts identified as having a contraindication or intolerance to intermittent pneumatic compression (IPC).
  - **Function:** Device providing neuromuscular electrostimulation of the common peroneal nerve -- promoting blood flow in deep veins located in the calf.

- **CliniTouch Vie** by **Spirit Digital**
  - **Aim:** Diminish disease deterioration, and unscheduled hospital admissions and re-admissions through accurate and timely escalation channels/interventions.
  - **Function:** Cloud based healthcare solution providing 24/7 virtual care for patients from their own home. The tailored care CliniTouch Vie planning system provides the capacity to monitor their vital signs with the added benefit consolidating real time information into their integrated care record for streamlined access from healthcare professionals.

- **Active+me** by **Aseptika LTD**
  - **Aim:** Alleviate the burden on NHS services by promoting self-management for patient cohorts who are commencing recovery post heart intervention or pulmonary exacerbation.
  - **Function:** Provision of remote group exercise classes, administered by a Physical Activity Specialist (PAS), built around evidence-based activities. These classes, in tandem with a suite of remote monitoring devices (pulse oximeters, blood pressure monitors, sleep trackers, etc.), provide clinical insights (following PAS reviewed patient data) into the physiological benefits patients receive.

- **Vscan Extend** by **MDi Medical Ltd**
  - **Aim:** Expediting the ability of healthcare professionals in making point-of-care treatment decisions, particularly within primary care through portable and

small form factor ultrasound imaging device. Bringing down referrals to secondary care and reducing waiting time for said referrals, earlier and more accurate diagnosis of cardiac problems, and improved precision in referral pathways are the anticipated downstream effects.

- **Function:** Handheld ultrasound imaging device with wireless integration and DICOM documentation, allowing for streamlined/instant sharing of gathered ultrasound images to relevant healthcare professionals (e.g. senior consultant), and archiving into patient records.

- **Stroke Pathway App** by **d2 Digital By Design Ltd**
  - **Aim:** Bolster paramedics' ability for compliance to the stroke pathway so that patients are triaged to a more accurate degree, and ultimately minimise the risk of acute stroke patients not receiving the specialist care at Hyper Acute Stroke Units (HASUs) that is necessary.
  - **Function:** d2 Digital By Design Ltd have developed a mobile app that functions as a decision support tool around the stroke pathway to aid in the provision of correct patient care. Paramedics can expect to accelerate their decision making as the pathway questions presented in the app are approximated to take 10 seconds from start to finish.

- **AliveCor Mobile ECG** by **AliveCor**
  - **Aim:** Improve detection of undiagnosed AF, enhance prevalence scores, and expand the scope of this cohort to put through channels that provide effective management.
  - **Function:** Small form factor AF detection device that pairs with an app installed on a smart phone, capable of providing immediate detection and diagnosis of AF during opportunistic screening visits in primary care. Process is straightforward and involves patient simply holding the device for ~30 seconds.

- **e-ASPECTS** by **Brainomix**
  - **Aim:** Development of an innovation that promotes access and availability to CT scans and specialist feedback for stroke patients and frontline staff within healthcare. Utilisation of the e-ASPECTS technology aims to promote earlier diagnosis, severity, and treatment for stroke patients.
  - **Function:** e-ASPECTS dwindles the buffer time to treatment protocols that stroke patients experience by integrating the Alberta Stroke Programme Early CT Score (ASPECTS) scoring system on brain images taken from acute ischemic stroke patients.

- **HeartFlow** by **HeartFlow**
    - **Aim:** Streamlining the cost and time implications involved for accurately diagnosing a patient with coronary artery disease (CAD) with a non-invasive innovation, as opposed to invasive and higher risk procedures such as diagnostic coronary angiography.
    - **Function:** At its core, HeartFlow employs the use of deep learning in conjunction with technical staff to allow for bespoke 3D modelling of a patient's coronary arteries, based off their CT. From this, HeartFlow can simulate blood flow in the model to deduce the extent of blockage. HeartFlow now sits within the NICE guidance framework as a diagnostic technology for acute coronary syndrome, with an estimated cost saving of £214 per patient [34].

- **MyDiagnostick** by **MyDiagnostick Medical B.V.**
    - **Aim:** Simplify the process by which GPs, cardiologists, neurologists, and nurses can diagnose AF and underlying causes of stroke, as well as the patient documentation process.
    - **Function:** A stick-shaped, portable, and handheld ECG recorder featuring electrodes on opposite ends which the patient grasps with both hands for 1 minute, after which the device with flash green (no AF detected) or red (AF episode detected). The MyDiagnostick device has the capability of storing ≥100 ECG recording which can then be transferred and stored through USB connection.

5.4 UK Funding Bodies for Innovations in MedTech

Sourcing funds is an inherent requisite for the successful development of an innovative medical device, particularly for SMEs. This is because medical devices must pass several distinct milestones (regulatory and ethical approval, clinical studies, CE markings, etc.) before being accessible to the market due to the safety implications, as well as to demonstrate performance. Several key bodies and programmes exist to facilitate the funding and development process for innovations demonstrating high promise – Innovate UK (SME funding), NIHR i4i (academic, NHS and/or SME collaboration funding), and SBRI Healthcare (SME funding) -- further detailing of these funding bodies are provided below.

Navigating the plethora of funding programmes provided by each of the bodies listed can be an exhaustive endeavour. In order to elucidate where and what pools of funding are being funnelled towards within CVD, please refer to tables 3, 4, and 5 in the Appendix where we have consolidated key information from funded projects with respect to the main funding bodies highlighted below.

Innovate UK

As a funding initiative backed by the UK government, Innovate UK operates under the United Kingdom Research and Innovation organisation – a non-departmental public body responsible for provisioning funding into research and innovation that falls upstream from the science budget provided by the UK's Department for Business, Energy, and Industrial Strategy. Innovate UK's goal is signpost businesses with innovations that hold potential to spur on economic growth and productivity [35].

NIHR Invention for Innovation (i4i)

For early stage healthcare innovations (medical devices, diagnostic capabilities, e-health, etc.) looking to tackle identified areas of unmet clinical needs and that seek funding to mitigate risk factors and drive commercial adoption within the NHS, NIHR's i4i programme, backed by the Department of Health and Social Care, may be the right choice. For collaborative projects (a combination of any two: SMEs, NHS providers, or higher education institutions) to be applicable for i4i funding, a demonstrable proof-of-concept and detailed route to adoption and commercialisation are required [36].

SBRI Healthcare

Initiated in 2008, the Small Business Research Initiative (SBRI) scheme, funded by NHS England, has gone on to fund £17.5 million per year on average to more than 200 SMEs looking to provide solutions to unmet needs within the NHS. From these, several SBRI backed companies have gone on to commercialise their innovations to healthcare industries across the world. SBRI Healthcare hosts numerous competitions calling for companies to demonstrate their advances in discrete clinical areas, with everything from CVD detection and prevention to competitions specifically aimed at addressing functional needs in the elderly [37].

5.5 MedTech/Innovation Companies to Monitor

Lifelight | https://lifelight.ai

40 seconds – that's all it takes for Lifelight's innovative digital healthcare platform measures a patient's important vital signs. Better yet is its contactless method of use, of particular importance in a world where infectious diseases currently garner the healthcare spotlight. As a result, Lifelight have managed to produce the world's first in contactless vital sign measurement (i.e. blood pressure, pulse, respiration count, and oxygen saturation) just by the patient gazing at a smartphone or tablet device – an innovation showing great potential for remote consultations in primary care, an important goalpost within the NHS Long Term Plan.

Having been provided successful CE marking and MHRA regulatory approval, Lifelight is finding particular success and uptake, spurred on by the pandemic, within care homes. It's stake, however, is not limited there – HCPs in primary and secondary care are finding that Lifelight is helping minimise clinical time with patients while not compromising on all-important clinical accuracy. In total, Lifelight's innovation is now being utilised over 15 care homes, 2 secondary care facilities, and 2 GPs and is receiving follow on funding from Innovate UK (one of the funding bodies outlined in the previous section).

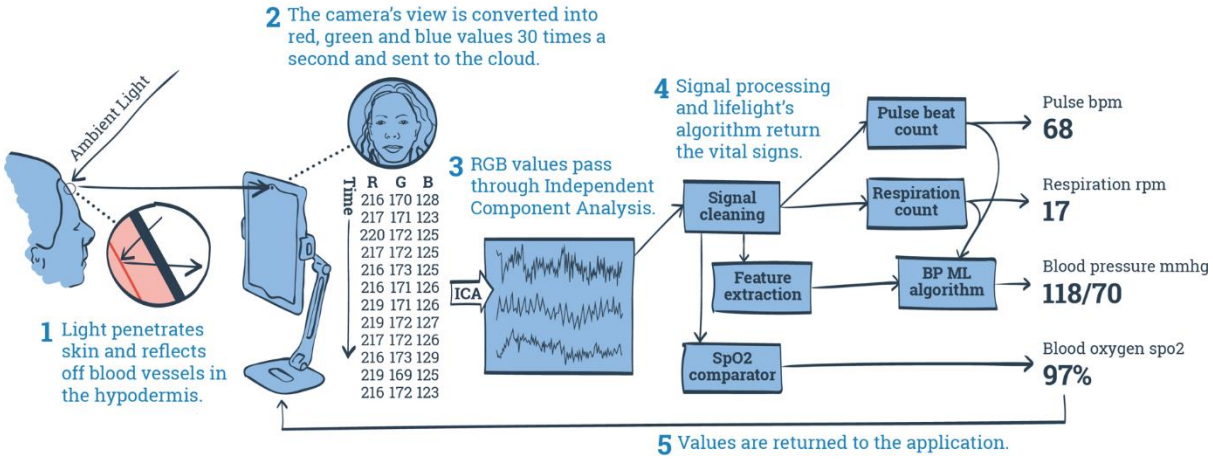

Figure 6 – Overview of the interface and underlying technology functions to obtain clinically relevant vital sign measurements from the patient (Source: Lifelight® [38])

Anidium Limited

YoHeart™ - Anidium's wearable ECG device designed to accelerate clinical diagnosis of arrhythmia (namely AF) at greater cost-effectiveness to the healthcare system than currently implemented solutions via mitigating downstream medical complications.

Funding and support for Andium's innovation was prompted by HEE's very own MedTech Navigator funding initiative (through support of the European Regional Development Fund (ERDF)) as part of a larger funding allocation of £160,000 reserved for companies showing great promise in taking on high priority issues facing healthcare. Funding will go towards the collection of Anidium's first empirical data on patient use for YoHeart™ in collaboration with expert cardiologists at Royal Papworth NHS Foundation Trust.

It is hoped that Anidium's medical device will help shift the dynamic surrounding the detection and treatment of AF from reactionary to preventative; works from Public Health England estimate that earlier detection of just 1 out of every 25 patients could help save more than £240m within 3 years for the NHS.

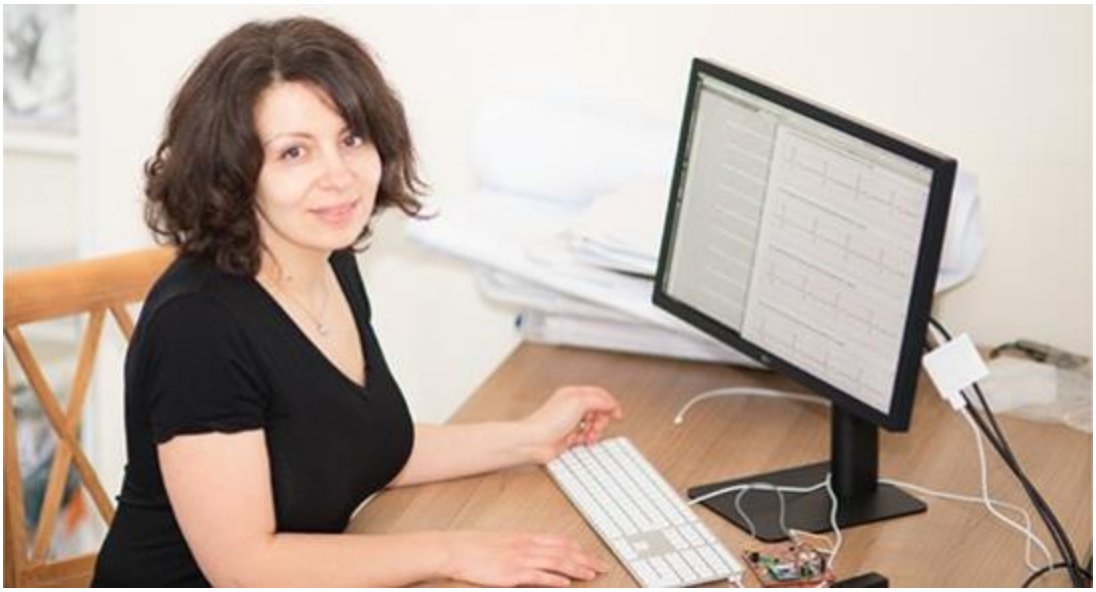

Figure 7 - Dr Elena Punskaya, Co-Founder and Chief Technology Officer of Anidium Limited, pictured with the first working prototype of the YoHeart™ device (Image source: University of Cambridge [39])

Docobo | https://www.docobo.co.uk

The provision of remote monitoring solutions is seen as a critical move towards establishing a healthcare system and patient population that is focussed on participating in proactive programmes within primary care. Recognising this shift and capitalising on it, Docobo have brought one such innovation to light – Aegle. Through a collaboration with Crawley, Horsham and West Sussex CCGs, the premise behind Aegle is to help better identify patient populations at risk of CVD issues through a combination of screening, assessment, monitoring, and health insight tools. Through Aegle, Docobo expects noticeable reductions in visitations to A&E because of this proactive intervention and, thus, easing the burden on clinical workloads.

As part of Docobo's greater digital toolkit, they have successfully rolled out, across the NHS and care homes, DOC@HOME® -- their flagship remote patient monitoring and case management system that can be installed on any number of smart devices. A pilot study focussed on promoting patient self-management by way of DOC@HOME® for those with COPD showcased a 78% reduction in hospital admissions.

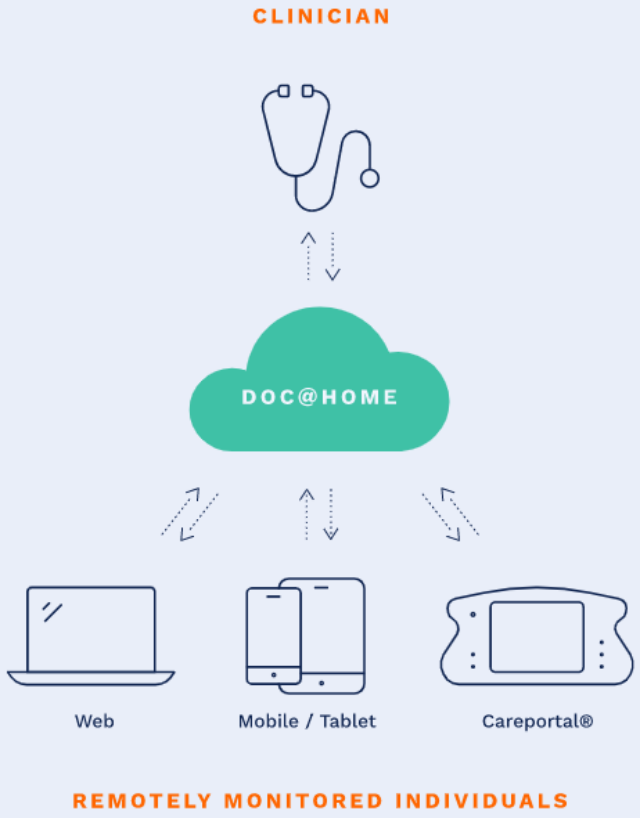

Figure 8 – High level illustration demonstrating the basic premise behind DOC@HOME®'s capacity for remote patient monitoring (Source: Docobo [])

Helicon Health | https://heliconhealth.co.uk

Efficient mitigation, management, and treatment protocols for those at risk or suffering from stroke is a key focus for the NHS, with an economic impact of roughly £2bn on the healthcare system and £6bn on social care costs due to high rates of avoidable deaths and disabilities resulting from poor clinical management. Enter Helicon Health – based in London, their aim is to curb stroke rates through HeliconStrokePrevent by at least 10%.

HeliconStrokePrevent is best described as a patient-centric eHealth platform being developed with stroke patients, those with a high risk of stroke, and even cohorts with atrial fibrillation in mind so that they are provided with tools to better manage their condition. Self-management is centred on aspects such as blood pressure, anticoagulant control (Helicon Heart), activity and lifestyle, education around their health condition, and channels of communication/collaboration between themselves and clinicians (Helicon eLearning).

Helicon Health's digital innovation was accelerated into development after having been awarding funding from SBRI Healthcare in 2016 under their "GP of the Future – Self Care" competition – a pool of innovations now comprising up to £8.6m in total funding with the purpose of transforming GP and primary care services.

AIMES | https://aimes.uk/

Through an extensive collaboration between AIMES, Barts Health NHS Trust and UCL, a near £100,000 funding through SBRI's cardiovascular disease spring 2019 competition was awarded to the result of this partnership – OpenCARE. It headlines as providing AI precision diagnostics for cardiovascular care; put simply, OpenCARE looks to provide a point of care service that delivers increased precision, accuracy, turnaround, and prognosis for MRI heart function measurements. How has this been achieved? AIMES' solution comes by way of AI integration – developing a proprietary algorithm built upon a bedrock of being trained on 2 million images collected from 10 sites.

AIMES' innovation is estimated to effect approximately 20% of key clinical decisions revolving around CVD related issues. Iterative roll-out and adoption of the OpenCARE service across the NHS continues through utilisation of said service within Trustworthy Research Environments (TRE) and cooperation with 20 cardiology centres across the UK.

6. Number of In-Progress Clinical Trials in CVD (UK)

To evaluate the number of trials occurring around CVD related ailments that were actively recruiting patient cohorts at the time of writing this section in the whitepaper [7th June 2021], data was pulled from the NIHR Clinical Trials database []. The landscape of these results, separated by innovation type, are shown in Figure 9. Total trials (including drug and drug delivery trials) for each of the CVD risk areas were as follows:

- Chronic kidney disease – 38
- Congenital heart disease – 7

- Familia hypercholesterolaemia – 1
- Atrial fibrillation – 43
- High blood pressure – 25
- Cardiovascular disease – 83
- Diabetes (Type 1 and Type 2) – 175

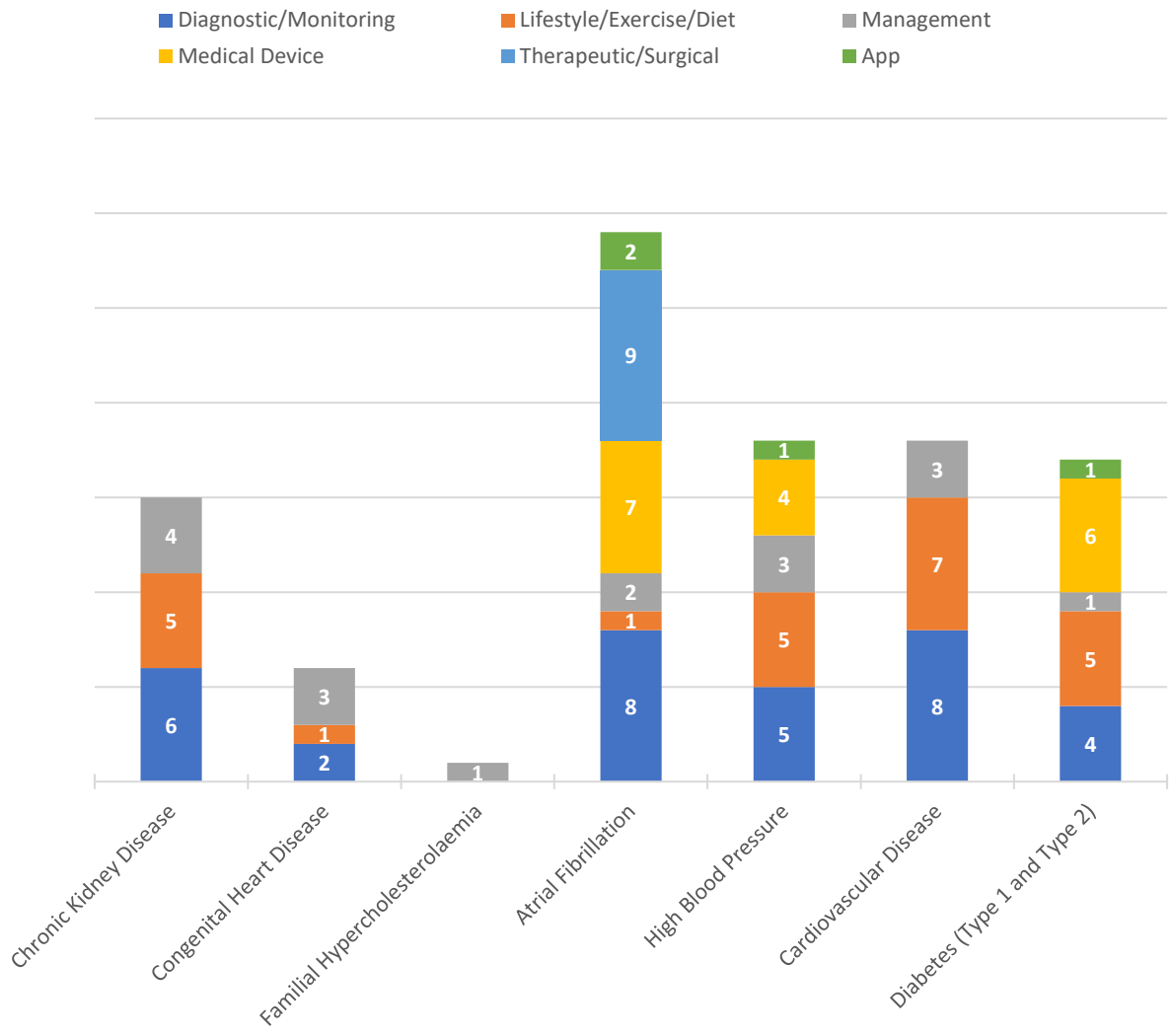

Figure 9 – Distribution of trials, split by innovation, actively recruiting for patient cohorts within specific CVD risk areas (excluding drug and delivery trials). Data adapted from NIHR Clinical Trials Database [accessed 7th June 2021]

7. Patent Landscape Review

Having a system in place to categorically define and identify medical devices allows us to evaluate where focus in innovation is being placed within CVD and the clinical risk areas that fall under it. To allow us to tap into the heart of the patent scene, data was extracted and tabulated using what is known as the Cooperative Patent Classification (CPC) system – an internationally recognised and implemented classification system for patent publications, born out of a collaboration between the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO).

7.1 Where the most IP is being filed within CVD

There exists a plethora of classifications (~250,000) within the CPC system of classes and sub-classes that follow upstream from nine distinct classification sections. In order to adequately tune out the signal from the noise, results were filtered down from several select medical classes. These include class A61B (diagnosis; surgery; identification), A61F (filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g. stents), and A61M (devices for introducing media into, or onto, the body, e.g. dialysis systems, and kits for diabetes), as well as any pertinent sub-classes within them. Subsequently, a patent repository/database was used to extract the necessary data counts to ascertain the highest levels of patent activity for medical devices within CVD published between 2019 – 2021 (Table 4). As shown, the sub-class demonstrating the most filing activity for medical device innovations were based on those serving a diagnostic/monitoring function.

	CPC Class (Main) Code	CPC Sub-Class Code	Number of Records	Description of Area
1	**A61B**	_____	1062	Instruments, implements, and processes for diagnostic, surgical and person-identification purposes
1.1		5/00	82	Measuring for diagnostic purposes
1.2		5/361	14	Detecting fibrillation
1.3		5/364	6	Detecting abnormal ECG interval, e.g. extrasystoles or ectopic heartbeats
1.4		5/366	8	Detecting abnormal QRS complex, e.g. widening
1.5		5/0044	4	Imaging apparatus/acquisition for the heart
1.6		5/02	41	Detecting, measuring or recording pulse, heart rate, blood pressure or blood flow (e.g. electrocardiography)
2	**A61F**	_____	168	Filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g. stents
2.1		2/24	2	Heart valves
2.2		2/07	15	Stent Grafts
2.3		2/95	2	Instruments specially adapted for placement or removal of stents or stent-grafts
3	**A61M**	_____	452	Devices for introducing media into, or onto, the body, e.g. dialysis systems, and kits for diabetes

3.1		5/003	15	Kits for Diabetes
3.2		1/14	5	Dialysis systems; Artificial kidneys; Blood oxygenators

Table 4 – Quantification of where IP filings/innovations within CVD have been most prominently published from 2019 – 2021 [], []

7.2 Companies Filing the Most Patents within CVD Over Previous 2 Years

To paint a commercial overview, it was important to identify key players in the market that have been actively publishing innovations within CVD between 2019 – 2021. We were able to extrapolate data from the patent database to help us identify the top 5 companies (ordered by # of patents published) in CVD within classes A61B, A61F, and A61M, cumulatively:

1. Medtronic
2. F. Hoffman-La Roche Ltd.
3. Dexcom Inc.
4. Bigfoot Biomedical Inc.
5. Omron Healthcare Co Ltd.

1. Medtronic

Of the 39 patents filed by Medtronic, a majority of the innovations were categorised for diagnostic and monitoring purposes be it in the form of systems, devices, methods, and/or apparatus. Of these, a significant number were concerned with the detection, monitoring, and treatment of hypertension.

2. F. Hoffman-La Roche Ltd.

Roche published a total of 30 patents over the 2-year timeframe with a particular focus on the monitoring of diabetes, and hyperglycaemia. Said monitoring patents involved utilising smart devices (e.g. mobile devices), standalone diabetes management systems, and specific protocols (i.e. methods) for their useability.

3. Dexcom, Inc.

Similar in vein to Roche, Dexcom's 27 published claims were primarily fixated on aspects from alert systems for hyperglycaemia prevention to integrated medicament systems in order to monitor, treat, and manage diabetes. Of particular interest was a novel protocol to wirelessly transmit analyte data to an array of devices from which a user, with appropriate levels of permission, could adjust sensory parameters via a management software interface.

4. Bigfoot Biomedical, Inc.

With 19 patents under their name, Bigfoot Biomedical has filed a collection of patents that are central in mitigating the problems associated with managing hyperglycaemia and reducing the likelihood of said events, typically via systems analysing patient glucose data and transmittance of an alarm based on patient specific blood glucose level thresholds.

5. Omron Healthcare Co. Ltd.

While fifth on the list with a relatively modest 10 patent filings, Omron is looking to make strides when it comes to diagnostic measurements around high blood pressure. Examples of such innovations include patenting a pouch-shaped structure, used in conjunction with a sphygmomanometer, as well as its use method in order to provide higher precision blood pressure readings; and an information processing technique (involving patent on the equipment, method, and processing program) that can provide diagnostic insight into the *type* of hypertension a user may have.

7.3 Most Active Companies by Specific CVD Area

Building on top of the higher-level patent landscape established in the previous section, more granular levels of insight were established to determine which specific risk areas within CVD patents are being filed under by healthcare companies. To develop a clearer picture on this, a 5-year range (2016-2021) was defined. Collectively, Medtronic had filed a total of 624 patents across the range of CVD risk conditions outlined below – far and above the most prominent company publishing innovations within CVD. Sanofi, while not present in 5 out of the 6 top 5 lists, was by and large the dominating company for innovations within FH – many of their published items revolved around novel drug delivery devices and their mechanisms, presumably due to Sanofi's exposure within this market with their injectable prescription medicine.

Top 5 Applicants in High Blood Pressure/Hypertension

1. Koninklijke Philips (305)
2. Medtronic (229)
3. Samsung Electronics Co. Ltd. (74)
4. Boston Scientific Scimed Inc. (67)
5. Omron Healthcare Co. Ltd. (65)

Top 5 Applicants in Atrial Fibrillation

1. St. Jude Medical (308)
2. Biosense Webster Ltd. (259)
3. Medtronic (185)
4. Boston Scientific Scimed Inc. (132)
5. Cardiac Pacemakers, Inc. (11)

Top 5 Applicants in Familial Hypercholesterolaemia

1. Sanofi S.A. (237)
2. HDL Therapeutics, Inc. (6)
3. Global Bio Therapeutics (3)
4. AngioDynamics (2)

5. Regeneron Pharmaceuticals, Inc. (2)

Top 5 Applicants in Non-Diabetic Hyperglycaemia

1. Dexcom, Inc. (146)
2. Abbott Laboratories (139)
3. Medtronic (112)
4. F. Hoffman-La Roche Ltd. (61)
5. I-Sens Inc. (40)

Top 5 Applicants in Diabetes (Type 1 and Type 2)

1. F. Hoffman-La Roche Ltd. (37)
2. Dexcom, Inc. (26)
3. Medtronic (25)
4. Abbott Laboratories (23)
5. Bigfoot Biomedical, Inc. (22)

Top 5 Applicants in Chronic Kidney Disease

1. Medtronic (73)
2. Strataca Systems Ltd. (24)
3. Amgen Inc. (23)
4. Fresenius Medical Care AG & Co. KGaA (19)
5. Koninklijke Philips (17)

8. Conclusions

Numerous milestones are to be met going forwards for the NHS and social care system at large when it comes to surmounting rises CVD prevalence and mortality across England. This is of particular importance when it comes to the methods, technology, and infrastructure in place for effective diagnosis, treatment, and prevention of the clinical risk areas (e.g. AF, hypertension, etc.) highlighted throughout this report. One of the ways in which a significant push has been made towards correcting this course has been through the surge of mHealth and digitally enabled care that have expedited aspects such as triaging accuracy and throughput, as well as providing clinically validated and secure repositories of patient data collected in controlled environments or through effective self-monitoring devices.

With all this in mind, MedTech enterprises operating uniquely within the CVD space will find themselves having to deal with new standards of expectations, metrics, and pathways within the healthcare ecosystem should they wish to reach or maintain a competitive edge.

There is no one size fit all solution in this regard, while services revolving around digitally enabled care can accelerate engagement with both clinicians and patients alike for one company, another may find success and untapped value by considering a broader and inclusive approach to CVD management. Similarly, as the gamut of responsibility for CVD management is broadened within healthcare via increased responsibility on nurses and junior doctors, enterprises are finding themselves re-evaluating their strategies as to who their key demographics are having previously been more focussed on specialist healthcare professionals, such as cardiologists.

9. Appendix

Table 5 – Innovate UK grant winners (including SBRI for projects delivering innovations within CVD and potentially improving associated healthcare outcomes

Award Title	Company	Title of Project	Grant Total
Innovate UK Smart Grants: January 2020	Cristal Health Ltd.	Akrivia Health: Instrumentalising mental healthcare data with AI (DOMI)	£349,875
Innovate UK Smart Grants: January 2020	Metadvice Ltd. / King's College London	Metadvice Lipid Management AI application for doctors to manage patients at risk for developing heart disease	£348,219
Innovate UK Smart Grants: July 2019 (Stream 1: 6-18 Months)	Echopoint Medical Ltd.	Miniaturisation and design-for-manufacture of a fibre-optic pressure and flow sensor for guiding minimally invasive cardiovascular therapies	£221,562
Innovate UK Smart Grants: April 2019 (Stream 1: 6-18 Months)	Spyras Ltd.	Development of a paper-based sensor for continuous breath analysis for monitoring patient health	£217,063
Innovate UK Smart Grants: January 2020	Digital & Future Technologies Limited	CAPE - Cardiac Analysis for Pressure Establishment	£202,479
Innovate UK Smart Grants: April 2019 (Stream 1: 6-18 Months)	Relative Health Limited	CAPE - Cardiac Analysis for Pressure Establishment	£192,399
Biomedical Catalyst 2019 Round 1 Feasibility and Primer Awards	BrainTrain2020 Limited / Sheffield Hallam University	Multiple physiological inputs to optimise real-time biofeedback through artificial intelligence to improve sleep in insomniacs	£179,439

UKRI Ideas to Address COVID-19 – Innovate UK Article 25 Funding Strand	M2JN Limited / Centre for Process Innovation Limited	COVID-19: Prediction of Respiratory Distress Episodes	£121,897
The Sustainable Innovation Fund: Round 2 (De Minimis)	Explain my Procedure Ltd.	Animation Supported Consent in Healthcare	£99,721
Business-Led Innovation in Response to Global Disruption (De Minimis)	Aseptika Limited	Deployment of Active+me for remote patient support and cardiac rehabilitation for vulnerable patients in isolation, following heart surgery.	£74,993
Business-Led Innovation in Response to Global Disruption (De Minimis)	Etexsense Limited	E-textiles based wearable electrode garment for rehabilitation and active living	£73,929
Business-Led Innovation in Response to Global Disruption - Round 2 (De Minimis)	B.P.P. Technical Services Limited	Aerosol Mist Separation Units for Enhanced Personal Protection in Indoor Environments	£73,667
Business-Led Innovation in Response to Global Disruption (De Minimis)	Isabel Healthcare Limited	Isabel EPIFFANY medical eLearning platform	£58,672
Innovate UK Smart Grants: January 2020	Storegene Limited / Novogene (UK) Company Limited	World's first Cardiovascular specific whole genome analysis service, Resource for Life	£53,922
Business-Led Innovation in Response to Global Disruption (De Minimis)	Amba Connected Care	An Early Warning and Emergency Response Service to Keep Older People Safe and Healthy at Home	£48,634
Analysis for Innovators Scale Up (SPF Wave 1) A4I Round 4	Deltex Medical Limited / NPL Management Limited	Innovation of a method to maintain focus of an Oesophageal Doppler probe	£41,976
SME Support to Evaluate Innovative Medical Technologies Round 5	ODI Medical Ltd.	The value of monitoring micro-circulation status in the management of trauma	£24,029
SME Support to Evaluate Innovative Medical Technologies: Round 3	Inavya Ventures Ltd.	AVATR CE Mark medical device: study planning and preparation (Option 1)	£18,081
Sum of Grant Total (2020 – 2021)			**£2,400,557**

Table 6 – NIHR i4i award funded projects for innovations within CVD

Award Title	Contracting Organisation	Funding
Stroke reduction via improved opportunistic screening for atrial fibrillation. An evaluation of the clinical and economic benefits of the RapidRhythm device within primary care.	Manchester University NHS Foundation Trust	£862,645
Non-contact measurement of aortic compliance	Barts and The London NHS Trust	£99,172
Feasibility of TURBOCARDIA installation in the descending aorta	Queen Mary University of London	£97,187
A non-invasive intracranial pressure (nICP) monitoring system	City, University of London	£464,590
MRI-augmented guidance for X-ray fluoroscopic paediatric cardiovascular interventions	King's College London	£400,719
A new neuromuscular, muscle pump stimulation device to improve haemodynamic stability in critical care patients	Barts Health NHS Trust	£253,459
Development of urinary microRNAs as biomarkers for diabetic kidney disease	Cardiff University	£171,450
Ascending Thoracic Aortic Graft (ATAG)	Barts Health NHS Trust	£747,497
Decision-assist software for management of acute ischaemic stroke using brain-imaging machine-learning	Imperial College London	£525,360
Clinical Assessment of a Novel Microprobe Array Continuous Glucose Monitor in Type 1 Diabetes	Imperial College London	£663,601
Non-invasive glucose monitoring using thin film laser	University of Leeds	£100,000
Sum of Funding Total		**£4,385,680**

Table 7 – SBRI Healthcare funded projects categorised under the SBRI cardiovascular pathway

SBRI Competition	Project	Company	Funding
Cardiovascular Disease (2019)	AI Precision Diagnostics for Cardiovascular Care (OpenCARE)	AIMES	£99,868
Research Tools (2013)	Affordable microfluidics for rapid, sensitive, point of care measurement of multiple cardiovascular disease biomarkers	Capillary Film Technology Ltd	£1,096,610
Cardiovascular (2013)	C2VS combined cardio and vascular	Cardiocity Ltd	£1,043,821
Cardiovascular Disease (2019)	Adaptive Neuronal Pacer for Heart Failure Treatment	Ceryx Medical Ltd	£100,000
Cardiovascular (2013)	Improving cardiovascular disease outcomes in primary care	Docobo	£99,648
Urgent and Emergency Care (2020)	eTriage: Exploring appropriate care rerouting within urgent and emergency care triage	eConsult Health Ltd	£97,106

GP of the Future - Self Care (2016)	myHelicon Stroke Prevention	Helicon Health	£98,725
Urgent and Emergency Care (2020)	POC test for diagnosis of myocardial infarction	Invitron Limited	£97,312
Cardiovascular Disease (2019)	Point of Care test for diagnosis of heart failure in primary care	Invitron Limited	£99,636
Cardiovascular Disease (2019)	Improving efficiency and efficacy of minimally invasive stent grafting interventions	Oxford Heartbeat Ltd	£100,000
Cardiovascular (2013)	Development of a very low cost (<£50), easy to use, lead-one ECG device	Plessey Semiconductors	£1,097,158
Urgent and Emergency Care (2020)	Prototyping of a novel single-molecule-counting point-of-care system to expedite the 0-1 hour algorithm for high-sensitivity troponin testing	Psyros Diagnostics	£99,400
Urgent and Emergency Care (2020)	Design and development of a Virtual Standardised Patient training platform to reduce pressures on emergency departments.	Recourse AI LTD	£94,960
Cardiovascular (2013)	Development of an online platform to support self-management of symptoms and promote wellbeing of people with cardiovascular disease (CVD)	SilverCloud Health	£93,621
Cardiovascular (2013)	Anatomically shaped disposable compression garments	Spintech	£100,000
Urgent and Emergency Care (2020)	Quantitative point-of-care (10 min) diagnostic test for cardiac troponin I and troponin T for high priority use cases.	Stream Bio Ltd	£99,715
Outpatients (2014)	Proactive monitoring of venous leg ulcers for more efficient use of outpatient resources	Ulsys	£99,996
	Sum of Funding Total		**£4,617,576**

References