



PWYLLGOR DIWYLLIANT, POBL A DATBLYGU SEFYDLIADOL PEOPLE, ORGANISATIONAL DEVELOPMENT & CULTURE COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	18 August 2022
TEITL YR ADRODDIAD: TITLE OF REPORT:	TriTech Institute Business Plan
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Professor Philip Kloer, Medical Director and Deputy CEO
SWYDDOG ADRODD: REPORTING OFFICER:	Dr Leighton Phillips, Director of Research, Innovation and University Partnerships and Prof. Chris Hopkins, Head of Clinical Engineering and Tritech Institute.

Pwrpas yr Adroddiad (dewiswch fel yn addas)

Purpose of the Report (select as appropriate)

Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA SBAR REPORT

Sefyllfa / Situation

To update the People, Organisational Development & Culture Committee (PODCC) on the five-year business plan for the TriTech Institute.

Cefndir / Background

The TriTech Institute (the Institute) was established by Hywel Dda University Health Board in 2021, to support healthcare technology development, research and innovation. The Institute aims to sustain the good interdisciplinary work between the research and development and clinical engineering departments beyond the pandemic, with the ultimate goal of supporting those innovations that can contribute to improved patient outcomes. The Institute was formally launched by the Permanent Secretary of the Welsh Government in November 2021.

While good progress has been made in establishing the Institute, a recent internal audit (June 2022) required the preparation of a five-year business plan, including the following:

- the scope, objectives and mission statement of TriTech;
- detailed financial breakdown including the establishment of budgets and resources;
- an exit strategy setting out the risk appetite and tolerances;
- required quality and safety standards are explicitly outlined; and
- key performance indicators.

Asesiad / Assessment

The business plan (Appendix 1) has been developed over a three-month period, in a consultative manner, and with independent advice from an external company called SBW. Moreover, the business plan benefits from the Institute having been in operation for a 12-month period. Within that period, the business model has been tested and refined, governance arrangements

strengthened, a team has been recruited and developed, and the Institute has secured several contracts. In its first year of operation, the Institute delivered a surplus against its cost recovery target and, perhaps more significantly, has committed to supporting clinical teams with technology innovations in areas including:

- the treatment of drug resistant depression through transcranial magnetic stimulation;
- a digital learning management system for those with chronic pain;
- technology enabled care for people with COPD, heart failure and frail older people;
- bioelectrical stimulation for the treatment of chronic knee pain;
- nasogastric feeding tube placement using a fibre optic device;
- diagnosis of prostate cancer utilising artificial intelligence; and
- diagnosis of early onset Alzheimer disease, using a gaming technology.

The level of interest in the initiative, and its developing reputation, has put it in a positive position for 2022/23, with the cost recovery target already met. The Institute's team are in the advanced stages of negotiation around two further contracts that, if agreed, will result in a surplus being generated in 2022/23 and significant contribution to the cost recovery target for 2023/24. It is noteworthy that the activity stimulated by the Institute has enabled the creation of several high quality scientific jobs within the region, supported the local economy through evaluative work completed for a number of local companies, and is leading to a growing base of clinical support. The latter often comment on the enabling nature of the initiative and teams, and how it is contributory to making Hywel Dda UHB an attractive place to work.

The business plan addresses the specific audit recommendations as follows:

- the scope, mission and objectives are set out within section one of the plan;
- the detailed financial breakdown is within section six, and the staffing establishment is set out within section five. The financial breakdown is reflective of the agreed establishment;
- an exit strategy and approach to managing risk is included within section five. This approach ties across to the performance management framework, described within section three;
- quality and safety standards are part of the new Quality Management system also described within section five. The ISO 13485 accreditation has been delivered; and
- the key performance indicators are set out within section three, which contain a balance of quality, operational and financial.

In advance of the business plan being considered by the People, Organisational Development and Culture Committee, it has been presented and agreed by the TriTech Management Group and the Executive Team. The Research and Innovation Sub Committee (R&ISC) received assurance from the content of the Business Plan at an extraordinary meeting convened on 18 July 2022 however requested that the following be considered in relation to its implementation:

- continuously pushing and boldly considering opportunities to grow activities, whether that is into new disciplines and specialties or sectors, with the potential to extend into social care;
- opportunities to realise recruitment and retention benefits, including providing dedicated time for clinical teams to pursue research and innovation interests;
- capitalising on the research, enterprise, and scientific opportunities presented by having such strong university partners operational within Hywel Dda UHB's area;
- re-investing surpluses to stimulating greater innovation across the UHB, with the suggestion that an investment panel could be established to guide this approach;

- the development of a performance framework to track through the delivery of the business plan and provide ongoing updates to the R&ISC and parent committees;
- the development of a public facing overview of the TriTech Institute's activities, with a focus on describing the benefits to patients and the public; and
- the production of tailored communication materials with a wider set of unique selling points USPs set out, including: the benefits of collaborating with an integrated health organisation; the 'rural' testbed available in South-West Wales; and the opportunities of having an integrated team, with scientific, research, and Value Based Healthcare expertise.

Members have also been shared the full version of the business plan, containing commercially sensitive information, for consideration and approval.

Next Steps

Following Board approval of the TriTech Business Plan, delivery against the performance measures contained within will be routinely reported to the Research and Innovation Sub Committee and PODCC.

Argymhelliad / Recommendation

For PODCC to receive assurance from the TriTech Business Plan and approve for onward submission to Board.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	2.5 To provide assurance that the organisation is discharging its functions and meeting its responsibilities with regard to the research and innovation activity carried out within the Health Board.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol: Datix Risk Register Reference and Score:	Risk 1156 – Score 4 Risk 1158 – Score 4 Risk 1142 – Score 4
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	2.9 Medical Devices, Equipment and Diagnostic Systems 3.3 Quality Improvement, Research and Innovation
Amcanion Strategol y BIP: UHB Strategic Objectives:	3. Striving to deliver and develop excellent services
Amcanion Cynllunio Planning Objectives	3G Research and Innovation
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	2. Develop a skilled and flexible workforce to meet the changing needs of the modern NHS

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Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	The Business Plan contains a market assessment based on a review of the evidence and a comparative assessment of competitors (Section Two)
Rhestr Termiau: Glossary of Terms:	Contained within the body of the report.
Partion / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Diwylliant, Pobl a Datblygu Sefydliadol: Parties / Committees consulted prior to People, Organisational Development & Culture Committee:	the TriTech Management Group The Executive Team Research & Innovation Sub-Committee

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	The financial plan has been assured by the Finance Department, which will track delivery against plan on a monthly basis. The summarised financial position is reported to the TriTech Management Group and the Research and Innovation Sub Committee.
Ansawdd / Gofal Claf: Quality / Patient Care:	The Business Plan contains an overview of the Quality Management System (Section 5) put in place for the initiative.
Gweithlu: Workforce:	The agreed establishment for the initiative is set out within Section 1 of the Business Plan and underpins the financial assumptions in Section 6.
Risg: Risk:	Section 5 of the Business Plan sets out the Risk Management approach.
Cyfreithiol: Legal:	<p>A contract is developed in respect of every TriTech project and reviewed by Legal and Risk Services. The legal basis for the Health Board to income generate is set out within the NHS (Wales) Act 2006, as amended by the 2014 Act:</p> <p>Part 11, Chapter 4: Power to raise money</p> <ul style="list-style-type: none"> • Applies to a Local Health Board, NHS Trust or Special Health Authority. • Has power to engage in activities intended to stimulate the giving (whether on trust or otherwise) of money or other property to: <ul style="list-style-type: none"> ➤ assist the body in providing or improving any services or any facilities or accommodation which

	<p>is or are, or will be, provided as part of the health service, or</p> <ul style="list-style-type: none"> ➤ assist it in connection with its functions with respect to research. <ul style="list-style-type: none"> • Subject to any directions of WMs excluding specified descriptions of activity, the activities authorised include: <ul style="list-style-type: none"> ➤ public appeals or collections ➤ competitions ➤ entertainments ➤ bazaars ➤ sales of produce or other goods, and ➤ other similar activities. • The activities may involve the use of land, premises or other property held by or for the benefit of the body exercising the power.
Enw Da: Reputational:	Applicable in the event of projects not being delivered to acceptable quality standard. A Communications Strategy and Quality Management System has been developed, as set out with sections four and five of the Business Plan.
Gyfrinachedd: Privacy:	Considered on a project-by-project basis and reflected in the contracts drafted with the input of Legal and Risk.
Cydraddoldeb: Equality:	Not applicable.



TRITECH
Sefydliad | Institute

Hywel Dda University Health Board

TriTech Institute Services

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Who We Are

In 2021 the TriTech Institute was launched. We are a team based in a bespoke facility within Hywel Dda University Health Board comprising of industry-leading engineers, scientists, and clinicians.

Our Institute

Here at the TriTech Institute, we support the development of solutions to improve patient and public outcomes, working with designers and manufacturers of healthcare products and innovations.

What We Offer

The team's advanced skills in clinical and research design are combined with technical engineering expertise to manage the whole innovative pathway from early unmet need, through to concept design, prototyping, clinical testing, and real-world service evaluations.

Our Services

We provide specific services and solutions for clinical engineering, research and innovation, and value-based healthcare, and can also support with grant writing and submission.

1.0 Current Organisation Details

1.1 National Context

The Well-being of Future Generations Act

Specific to Wales is the Well-being of Future Generations Act. This Act provides the ambition, permission, and legal obligation to improve our social, cultural, environmental, and economic well-being. The Well-being of Future Generations Act requires public bodies in Wales to think about the long-term impact of their decisions, to work better with people, communities, and each other, and to prevent persistent problems such as poverty, health inequalities, and climate change. The Act places a legal obligation upon public bodies to support research and innovation to develop an economy fit for the future.

An Innovation Strategy for Wales

To support the Well-being of Future Generations Act, the Welsh Government is developing a new integrated Innovation Strategy for Wales. This decision followed research commissioned by the Innovation Advisory Council for Wales and an extensive round of Stakeholder Engagement on the findings. The strategy will set out the direction and overarching priorities for innovation in Wales across sectors, the various Departments, delivery agents, and Ministerial portfolios, and will focus on delivering the Programme for Government.

The Logic Model will underpin the development of the strategy. It will be used to determine the desired outcomes from our innovation efforts and activity, informing the evaluation plan and target setting for the strategy, and communicating to our partners our main areas of focus.

A combination of the Well-being of Future Generations Act and the Innovation Strategy for Wales provides the optimal policy context for a West Wales and Hywel Dda UHB response.

Outcomes

Prosperous

- Increased new Products/Services to domestic and international markets
- New enterprise/jobs – net employment gain
- Increased procurement from Welsh Economy
- Increased spend on R, D & I
- Increased R, D & I income won
- Increased R, D & I activity in Wales
- Improved engagement with Innovation Skills
- Improved productivity (GVA)

Resilient

- Reduction in Carbon Emissions
- Improved Biodiversity

Cohesive

- Greater Cross-Sector Collaboration
- Improved Community Connectivity

Healthier

- Increased Adoption of Innovation
- Improved Patient/Citizen Outcomes
- Improved Patient/Citizen Experience
- Improved Resource Efficiency (NHS)

More Equal

- Fairer Distribution of Investment
- Diversity in Innovation
- Increased new to Innovation Companies

Vibrant

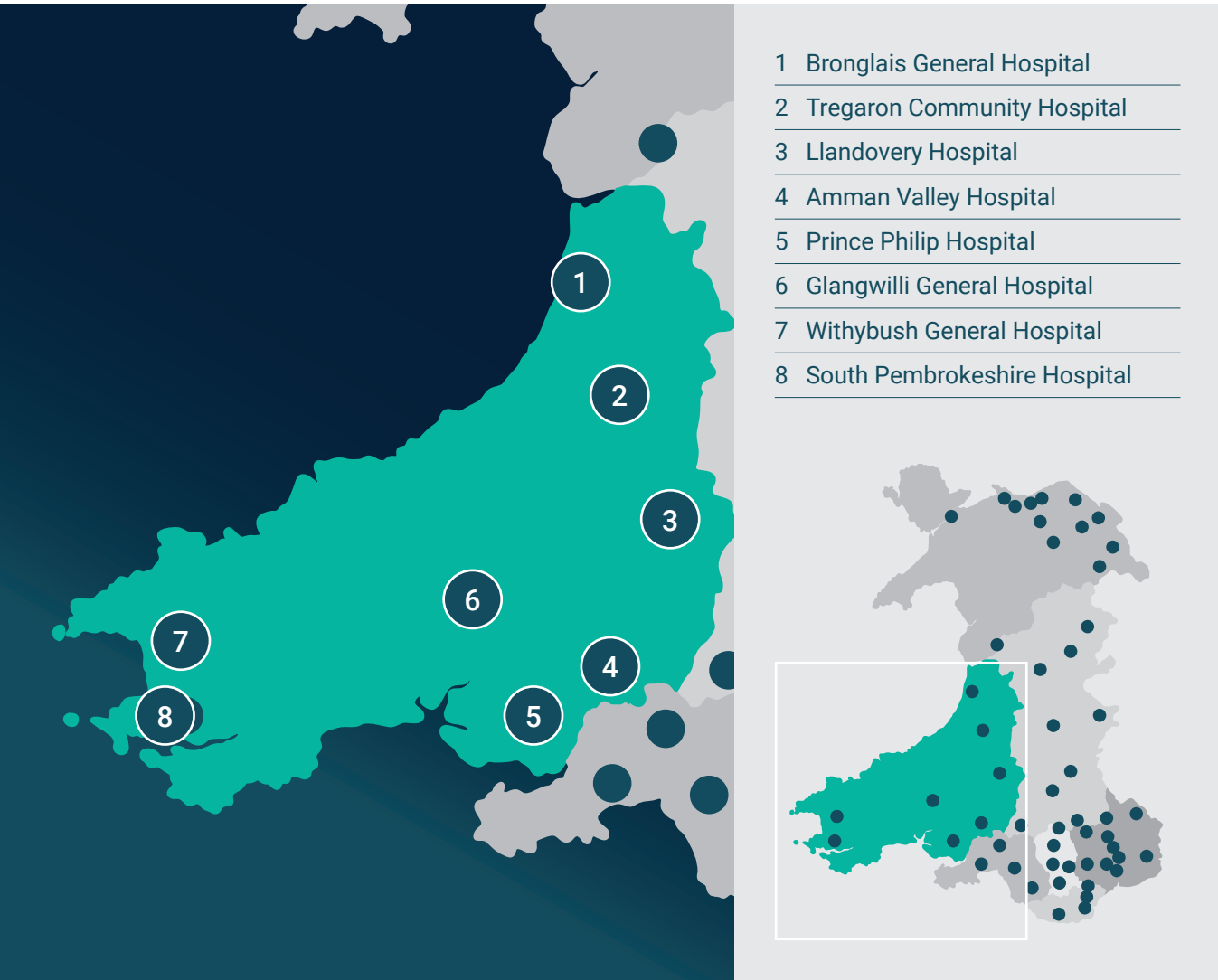
- Multi-lingual development as standard

Globally Responsible

- Informed Decision Making and Activities
- International Collaboration on Shared Challenges

1.2 Hywel Dda UHB Context

Hywel Dda UHB provides healthcare services to a total population of c.384,000 throughout Carmarthenshire, Ceredigion, and Pembrokeshire.



It provides Acute, Primary, Community, Mental Health, and Learning Disabilities services via General and Community Hospitals, Health Centres, GPs, Dentists, Pharmacists and Optometrists, and other sites.

Hywel Dda UHB's health and care strategy, 'A Healthier Mid and West Wales: Our future generations living well', sets out a plan to deliver excellent clinical services for the population of South West Wales. It also reaffirms Hywel Dda UHB's ambition to maximise the contribution it makes to the health and care system, by tackling the causes of ill health through promotion of health and well-being, prevention, and early intervention. In November 2020, set against this strategy and learning from the pandemic, the Board agreed several high-level objectives – describing the

horizon we are driving towards over the long term – as well as a set of specific, measurable planning objectives, which move towards that horizon over the next three years. One of the Strategic Objectives is to "Strive to deliver and develop excellent services", and within this, a planning objective was set to develop a strategy for research and innovation for Hywel Dda UHB. These objectives serve to place research and innovation at the heart of what Hywel Dda UHB does. The past two years have demonstrated just how critical research and innovation are to tackling the worst public health crisis the world has experienced in recent times.

The Research & Innovation Department enables staff and residents in the Hywel Dda UHB area to participate in research studies in health and social care, including those in cancer, respiratory disease, cardiovascular disease, gastrointestinal disorders, and ophthalmology. Hywel Dda UHB host a BioBank, have two Clinical Research Centres, and a new med-tech innovation facility (the **TriTech Institute**); Hywel Dda UHB has strong links with several local universities including three in its geographical area; University of Wales, Trinity and St David's, Swansea University, and Aberystwyth University, and formal partnerships are now being established with Bangor and Cardiff Universities.

The TriTech Institute has been established as a team with Hywel Dda UHB, mindful of the national and local policy and strategic context, to support the development and evaluation of innovative healthcare technologies, which contribute to improved patient outcomes.

"Truly innovative health technologies offer us the potential to have a powerful positive impact upon our patients, health system, and staff, thereby transforming healthcare for the future. It is at the heart of this organisation's values to do all we can to nurture and support such developments."

Steve Moore, Chief Executive, Hywel Dda UHB



Universities

- | | |
|---|--|
| 1 | University of Wales, Trinity and St David (Lampeter) |
| 2 | Swansea University |
| 3 | Aberystwyth University |

Clinical Research Centres

- | | |
|---|---------------|
| 4 | Haverfordwest |
| 5 | Aberystwyth |
| 6 | Carmarthen |
| 7 | Llanelli |

Clinical Engineering Centres

- | | |
|----|---------------|
| 8 | Haverfordwest |
| 9 | Aberystwyth |
| 10 | Carmarthen |
| 11 | Llanelli |

Hywel Dda UHB Research and Innovation Strategy

The direction and commitment to delivering practical steps to move our research, development, and innovation agenda forward is contained within the document *'Our Research and Innovation Strategy'*.

In November 2020, set against this strategy and learning from the pandemic, Hywel Dda UHB agreed several high-level objectives – describing the horizon it was driving towards over the long term, as well as committing to a set of specific, measurable planning objectives, which moves it towards that horizon over the next three years.

Strategic Goal 3 described Hywel Dda UHB's commitment to growing research and innovation activity in areas of strength and opportunity. While continuing to consolidate its research and innovation around key areas of strength, it commits to diversifying its activities to include new technology development. The actions set against this commitment included:

- Developing a new clinical engineering, innovation, and research facility, offering advice and support to developers of new health and care technologies;
- Increasing the number and quality of Value Based Health Care research, evaluation, and innovation projects;
- Developing targeted research and innovation growth plans in areas of clinical and academic strength, driven by population need, HCRW strategy/priorities, and UK prioritised need; and
- Developing targeted research in areas aligned with our wider corporate plans, which are refreshed on an annual basis (e.g. promoting green healthcare and the social model of health).

The action on developing a new clinical engineering, innovation, and research facility is being fulfilled through the establishment of the TriTech Institute.

1.3 Vision and Purpose

The TriTech Institute's vision is to support Hywel Dda UHB, other healthcare systems, and industry develop, test, implement, and evaluate innovative healthcare technologies at a local, national, and global scale. The TriTech Institute offers a single point of access to NHS and academic experts, a regional testbed, and an agile and efficient approach.

Elevator pitch

The TriTech Institute is a team of engineers, scientists, researchers, digital technologists and clinicians who make it easier to develop, test, and evaluate innovative technologies to improve their viability, including their contribution to patient outcomes, and support companies to thrive and create high quality jobs and growth.

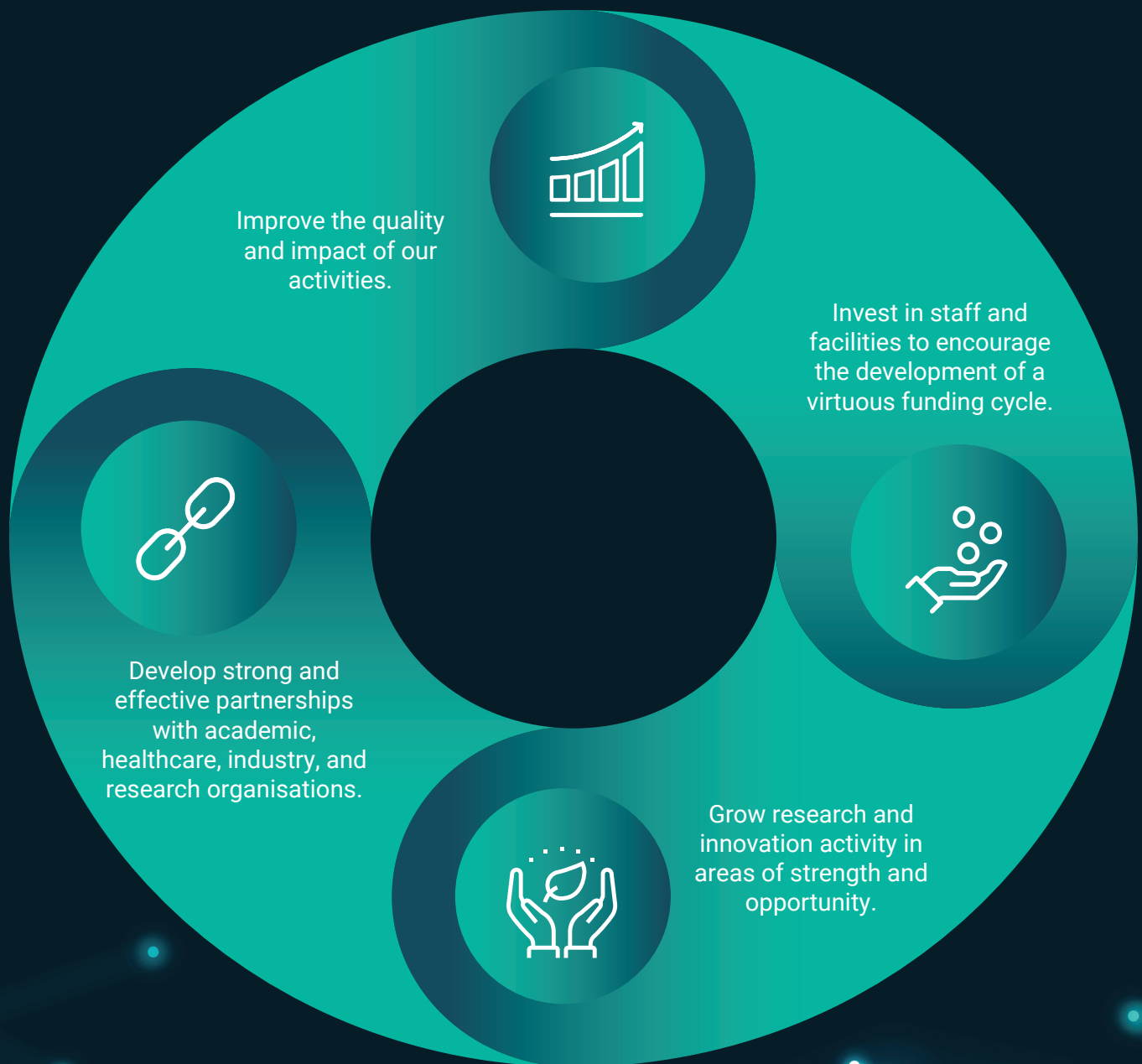
A more detailed account of purpose includes:

- supporting evaluations and clinical investigations of innovative medical technologies, leading to improved patient care;
- providing a single point of access to clinical services for medical technology designers and manufacturers;
- combining clinical and research design skills with technical engineering experience to manage the whole innovation pathway, from early unmet need, concept design, prototyping, and clinical testing through to established service evaluations;
- introducing and testing more established products and innovative medical technologies into real clinical systems;
- providing regulatory advice and route to market planning; and
- supporting economic growth and regional/UK investment.

Vision

We will produce and collaborate in high quality health and care research and innovation, to improve services and health outcomes for our public, patients, and staff.

We will realise our vision by delivering the following Strategic Goals:



As an initiative and a function of Hywel Dda UHB, the TriTech Institute's values reflect those of the wider organisation, including:

- Putting people at the heart of everything it does
- Striving to deliver and develop excellent services
- Working together to be the best it can be

Each of these values is evident in its work, practices, and behaviours.

The TriTech Institute embodies the following attributes in everything it does:

Professionalism: The TriTech Institute supports the development of healthcare solutions and Value-Based healthcare by offering a single point of access to the NHS in a professional and efficient way. It is transparent and accountable for all work undertaken to ensure expectations are met.

Cutting edge: The TriTech Institute is at the forefront of the latest research and innovation in the healthcare technology sector. It has a 'real world' focus throughout its work, which is driven forward by evidence. Its services are both decisive and rapid to ensure high levels of customer satisfaction.

Innovative: The TriTech Institute team members are always innovative, forward-thinking, and progressive in their approaches. A team of highly-skilled engineers, scientists, clinicians, and researchers ensure products are market-ready.

Personable: Connections are at the forefront of everything that the TriTech Institute does. Team members are personable and genuine in their outlook and seek to establish long-lasting relationships.

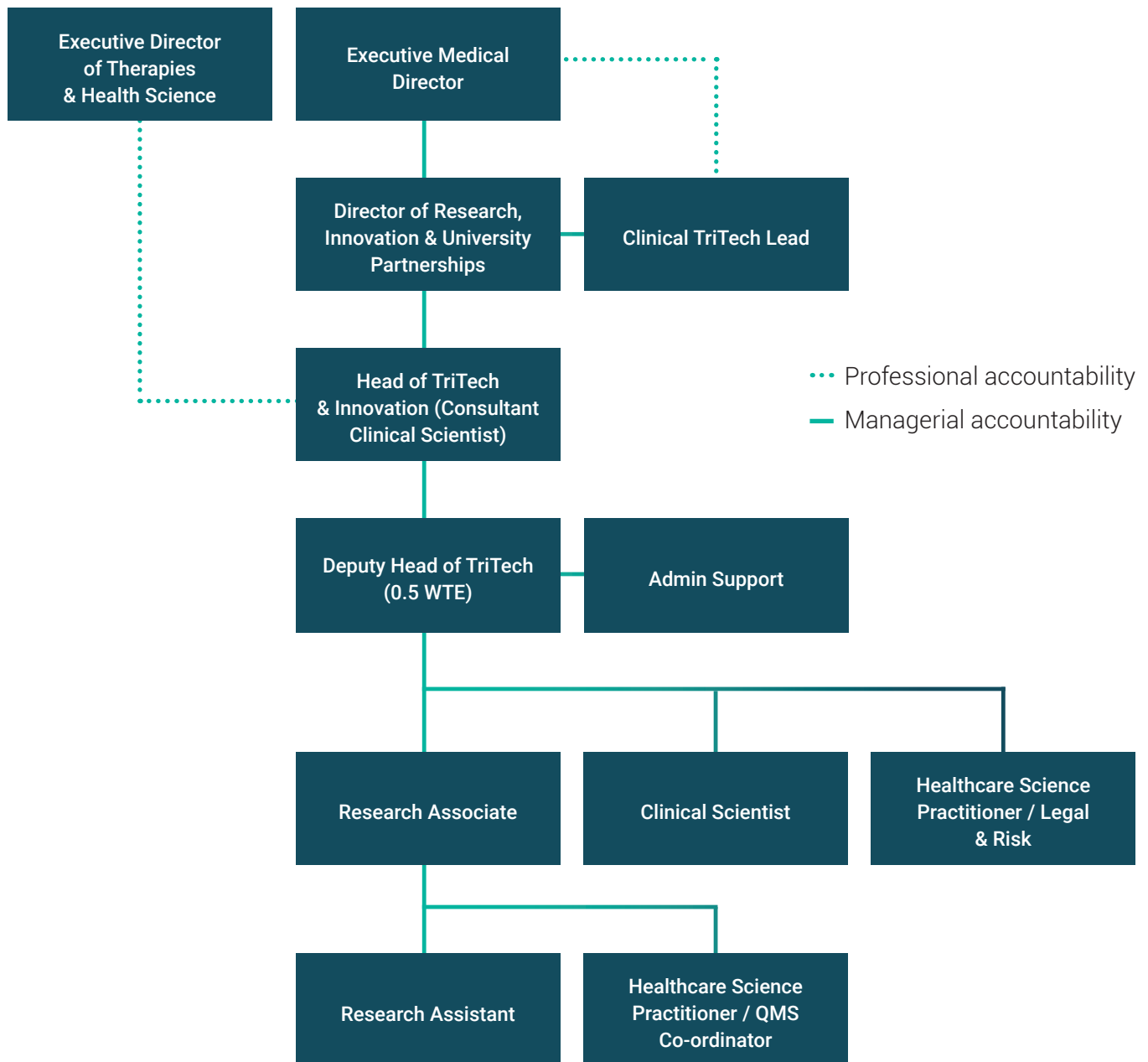
Management structure:

Under the current structure, the TriTech Institute sits within Hywel Dda UHB and under the management of the Executive Medical Director. The organisation chart on the next page highlights the reporting lines for all The TriTech Institute team members.

"Nearly every aspect of our healthcare system depends on technology but often we do not fully understand what impact it is having and how to best utilise it to improve patient and population outcomes. This lack of understanding can bring financial and human costs. The TriTech Institute is allowing Hywel Dda UHB to investigate and take steps to positively embrace technology. By working closely with our partners and life science companies, we are considering what works well and why. By helping industry to also understand this, we are supporting the development of viable products and supporting the development of high quality jobs within our region"

Professor Phil Kloer, Executive Medical Director and Deputy CEO.





1.4 Products and Services

The TriTech Institute offers four main products and services:

Research – this involves organisations commissioning clinical investigations to ensure the effectiveness and safety of their technologies. Crucially, the studies are designed as part of the regulatory approval process, which may lead to CE marking. The TriTech Institute will only offer this service when its ISO 13485 Quality Management System is in place in the summer of 2022. However, there are research projects the TriTech Institute team can support now. For example, when technologies have received their CE mark, an organisation might still wish to

commission research to produce generalisable findings, compare a technology to others in the marketplace, or recommend a change to routine care. In addition, there is the potential for the TriTech Institute to carry out a research project where healthcare professionals wish to introduce a new interventional procedure. In this case, the TriTech Institute will follow the 'New Interventional Procedures Policy' within the Health Board, which will involve review by the 'effective clinical practice advisory panel', chaired by the Associate Medical Director for Clinical Safety, ensuring the correct governance is followed. The TriTech Institute's team will support this process by designing and conducting research studies following Hywel Dda UHB's established study design, approvals, and set up processes.

Evaluation – this will involve organisations commissioning projects to understand the wider impact of their technologies, post regulatory approval, as part of routine care services. Such evaluations provide the opportunity to assess, for example, service and staff user experiences of the technologies (including patient reported outcomes), the costs associated with their introduction, and whether operational and service improvements result. As well as deriving the income associated with carrying out the evaluation, Hywel Dda UHB gains new insights on how these technologies enhance its care pathways. The TriTech Institute's team conducts evaluations according to Hywel Dda UHB's guidelines. As these guidelines are currently being refreshed, and recognising the specific characteristics associated with technology evaluations, the TriTech Institute's team has developed robust processes for setting up evaluations, with a comparable level of scrutiny to that followed for research.

University Partnerships – The TriTech Institute jointly funds posts with university partners to work on collaborative research and innovation projects. This allows both Hywel Dda UHB and universities within the region to pool expertise and resources and deliver greater impact than one organisation operating independently. The TriTech Institute is currently proactively partnering with the University of Wales Trinity Saint David and Swansea University.

Advice – this involves organisations commissioning very specific advice from the TriTech Institute. This might relate to the process for securing regulatory approval of a new technology or advice on how to conduct initial and basic bench testing of a technology in a laboratory setting. The TriTech Institute team will consider advisory requests on a case-by-case basis, and with due consideration of the team's expertise and subject to a satisfactory service level agreement with an organisation.

Intellectual property (IP)

While IP is not a service or product, it is important to recognise the positive contribution that identifying, protecting, and exploiting Intellectual property can make to the TriTech Institute. The activities and situations where IP could be generated include support for:

- the development of a new technology or device;
- a scientific discovery that underpins a new diagnostic test;
- the development of computational techniques, including software and artificial intelligence; and/or
- the development of know-how, including training materials and guidelines.

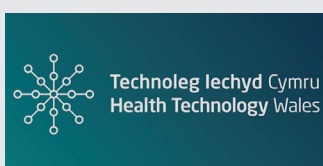
The IP rights are determined at the point of entering a collaborative agreement or contract. TriTech Institute has a direct relationship with NWSSP Legal & Risk to ensure a systematic and consistent approach to identifying and protecting IP. The Legal and Risk team on a case-by-case basis support all contract negotiations and agreements. A parallel piece of work is underway within Hywel Dda UHB to develop an IP policy and supporting guideline. This work will conclude in the autumn and the approach that the TriTech Institute takes to recognising and protecting IP will be reviewed at that point.



2.0 Market Analysis & TriTech Institute's Positioning

2.1 The Market Sector in Wales

There is a thriving Life Sciences, research and innovation, and medical technology community in Wales. The key organisations operating in this space include MediWales, the Life Sciences Hub Wales, Health Technology Wales, Health and Care Research Wales, the National Imaging Academy of Wales and, of course, the TriTech Institute, with whom these key organisations are intricately linked. There are also several university departments, think tanks and innovation centres to which the TriTech Institute needs to relate. In summary, the TriTech Institute works in collaboration with the medical technology community across Wales in order to provide a real-world test environment for any new medical technologies.



Life Science Hub Wales

The Life Science Hub Wales' mission is to "accelerate the development and adoption of innovative solutions for better health and wellbeing". It aims to transform the health and economic wellbeing of the nation through:

1. Accelerating the development and adoption of innovative solutions that support the health and social care needs of Wales;
2. Partnering with industry to advance economic development across the life sciences sector in Wales, driving business growth and creating jobs; and
3. Working closely with health and social care colleagues across Wales to understand the challenges and pressures an organisation may face. Once identified, working with industry to source and supporting the development of innovative solutions to respond to these challenges.

Health Technology Wales

Health Technology Wales (HTW) has a national remit and aims to improve the quality of care in Wales. It was formally launched in 2017 to deliver a strategic, national approach to the identification, appraisal, and adoption of non-medicines technologies across the Welsh care sector. HTW researches and undertakes desktop evaluations, utilising the best clinical and cost-effectiveness evidence, of non-medicine health technologies. Based on this evidence, HTW publishes guidance on whether health technology should be adopted for use in Wales. HTW is funded by Welsh Government and hosted within NHS Wales but is independent of both.

HTW supports evidence-informed decision making, which is essential for health and care providers to deliver safe and high-quality care services. Their remit covers any health technology that isn't a medicine, such as medical devices, surgical procedures, psychological therapies, tele-

monitoring or rehabilitation. The TriTech Institute has already collaborated with HTW by providing a real-world evaluation to support their desktop review of Transcranial Magnetic Stimulation.

Welsh Wound Innovation Centre

The Welsh Wound Innovation Centre (WWIC) plays a pivotal role in Wales' economic development, helping to accelerate growth by stimulating and supporting business-led innovation in wound care. Its vision is to transform the management and delivery of better wound health care via a coordinated, facilitated network approach that meets the needs of our stakeholders and customers.

WWIC's high level objectives are:

- To be recognised as a world leader in wound related health; and
- To engage with patients and stakeholders to provide a model that accelerates innovation, translation, improvement, and commercialisation in wound prevention, care management, and healing.

Hywel Dda UHB has an MoU with the WWIC and is hoping to collaborate on research and innovation projects.

Assistive Technologies & Innovation Centre (ATiC) (UWTSD)

The ATiC is a partner in the Accelerate project which helps innovators in Wales turn their ideas into solutions. ATiC is a research centre with expertise and experience in user-centred design, user-experience evaluation and analysis, 3D data and motion capture, as well as prototyping in a range of materials.

The TriTech Institute already has two jointly funded posts with the ATiC and is working on collaborative research and innovation projects with the centre.

Healthcare Technology Centre (Swansea University)

As a proud partner of the £24 million pan-Wales Accelerate programme, Swansea University has created the Healthcare Technology Centre (HTC),

which is based at its Singleton Park Campus. HTC supports the translation of promising ideas from the Life Science and Health sectors in Wales into new products, processes, and services, aiming to create long lasting economic value alongside broader societal benefits.

With a dedicated team of post-doctoral technologists, innovation and data science specialists, technicians and project managers, alongside its new high spec laboratory facilities, HTC compliments the technological development and adoption pipeline in Wales by supporting research, enterprise, and innovation activities, alongside related knowledge and skills development.

The TriTech Institute already has two jointly funded posts with the Health Technology Centre and is working on collaborative research and Innovation projects with the centre.

Respiratory Innovation Wales (RIW)

Respiratory Innovation Wales (RIW) is a not-for-profit limited company, which aims to:

- Enhance and develop respiratory products, services, or treatments;
- Seek real-world insights through advanced data science and digital engineering;
- Expand research and innovation activities;
- Provide advice and consultancy to organisations seeking expertise as they develop or enhance respiratory products and treatments;
- Provide education and training to organisations and individuals seeking real-world insights to benefit their practice and understanding; and
- Undertake its own research and collaborate with other organisations and academics for maximum impact.

Hywel Dda UHB has an MoU with Respiratory Innovation Wales and has already collaborated on a number of grant applications and innovation projects.

Bevan Commission

The Bevan Commission is Wales' leading health and care think tank, hosted and supported by Swansea University. They are committed to ensuring Wales can achieve its ambition of building sustainable, integrated health and care services that meet the needs of people across our villages, towns, and cities, positioning Wales amongst the best systems in the world.

The TriTech Institute has collaborated with the Bevan Commission on funding applications, a health technology challenge, and frequently supports 'Bevan Exemplars' with their technology innovation projects.

Technology Enabled Care (TEC) Cymru

Technology Enabled Care describes the use of technology by professionals and citizens to support the promotion, self-administration, monitoring, and delivery of health and care services.

TEC Cymru believed that using technology in this way can contribute to better:

- prevention, management, and control of harm or illness,
- slowing down the progression of care needs, and
- maintenance and promotion of independence in the home and community.

To support the implementation of Technology Enabled Care across Wales, the TEC Cymru core focus areas are:

- Telecare – remote real-time monitoring to manage the risks associated with independent living.
- Video Consulting – medical care carried out through video conferencing tools, allowing patients and clinicians to communicate and access healthcare online.

- Telehealth – the delivery of healthcare, health education, and health information services via remote technologies and platforms.

MediWales

MediWales describes itself as the independent life science network for Wales, bringing together industry, academia, and the clinical community to support the advancement of human life science in Wales and create collaborations and business opportunities for members.

Founded in 1992, MediWales is a not-for-profit limited company. It works on behalf of the Welsh life science sector, creating business opportunities and partnerships for its members, supporting global trade development, improving access to vital clinical expertise, and engaging with government to align support with sector needs.

Health and Care Research Wales (HCRW)

HCRW^W promotes research into diseases, treatments, and services, which can improve and save people's lives.

Health and social care research is, first and foremost, about improving the health and care of people and communities.

Their goal is to ensure that today's research makes a difference to tomorrow's care.

A networked organisation, supported by Welsh Government, HCRW bring together partners across the NHS in Wales, local authorities, universities, research institutions, third sector, and others.

Working in partnership with government agencies and research funders (in Wales and UK); industry partners; patients; service users; public and other stakeholders, HCRW promotes research into diseases, treatments, services, and outcomes that can lead to discoveries and innovations which can improve and even save people's lives.

HCRW funds a considerable R&D team within Hywel Dda UHB. Where the TriTech Institute supports the development of a new medical technology, and research is required, the R&D team will work closely to ensure robust research design and conduct.

National Imaging Academy of Wales

Artificial intelligence (AI) & Machine learning is widely understood to be key to reducing diagnostic waits, improving accuracy, and improving efficiency. This could be fundamental to Hywel Dda UHB's managed recovery from the Covid-19 pandemic. The TriTech Institute has identified a number of SMART objectives and one of those objectives is to increase the number of machine learning and artificial intelligence projects undertaken by Hywel Dda UHB, whilst working with the National Imaging Academy of Wales.

Established with £3.4m of funding from the Welsh Government, the Academy is Wales' flagship purpose-designed state of the art facility, which will meet the increasing need to train more consultant radiologists across the UK. Radiology Academies are well established in other parts of the UK, and widely viewed as a successful model for radiology training, research, and innovation nationally.

"The mission is a bit more important in Wales. Organisations can never quite explain, why Wales? It's 90 pages about the project and you're still left asking the question - why do it here?"

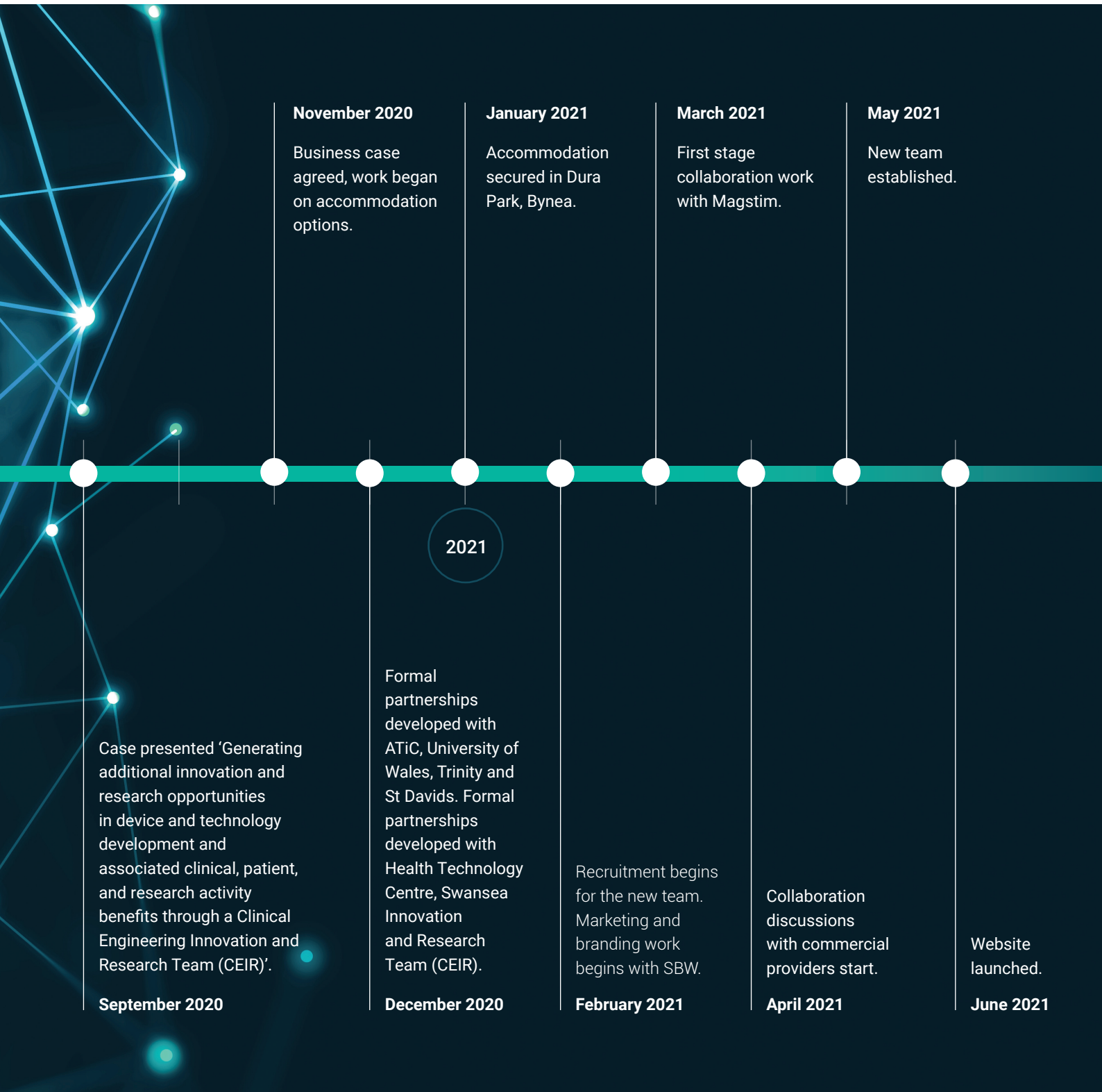
James Davies, Business Wales



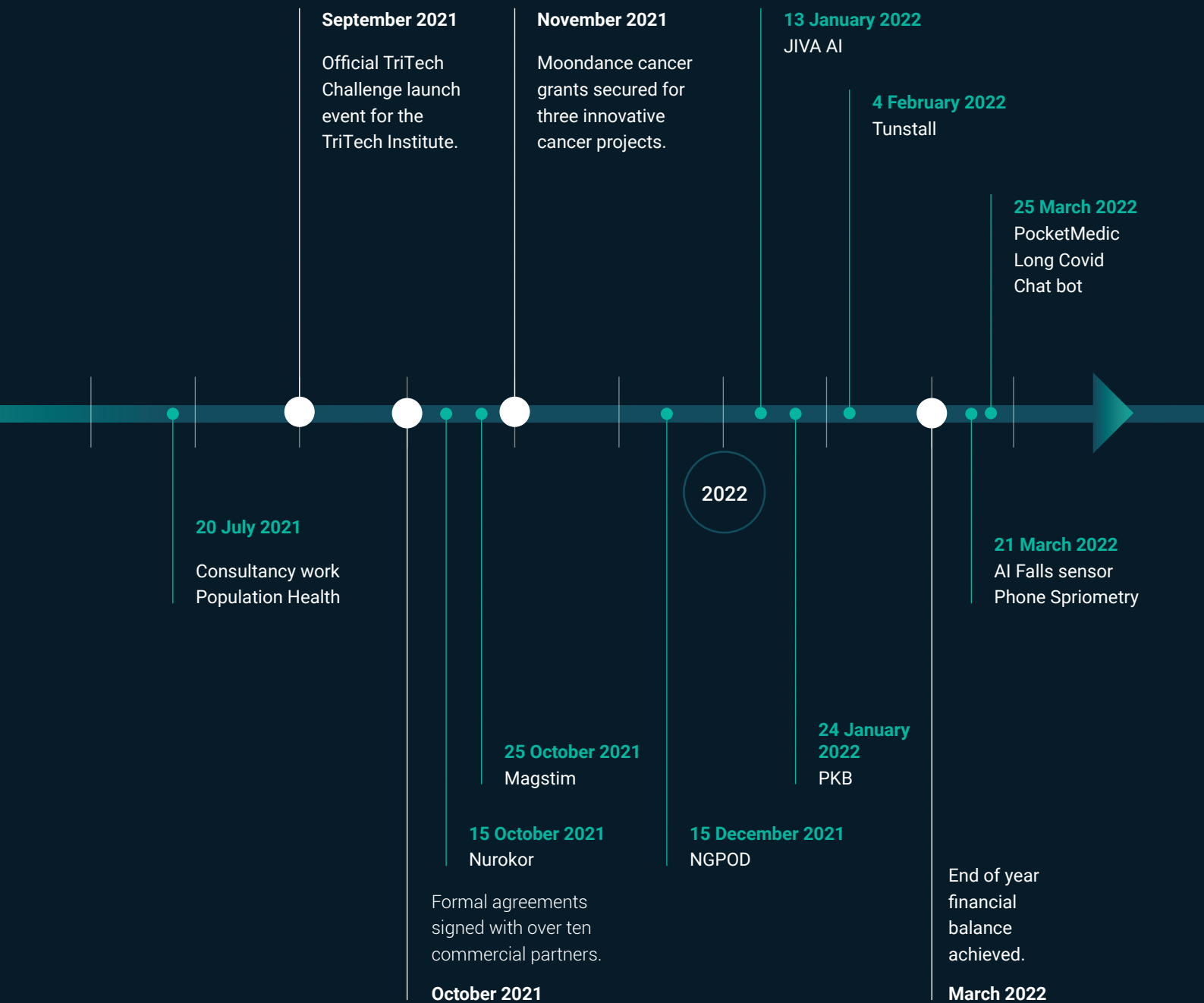
2.2 The TriTech Institute Positioning

The TriTech Institute was originally created as a hub bringing together Clinical Engineering and R&D, tasked with generating additional innovation and research opportunities in device and technology development. Now operational

for almost one year, this section will draw on the current market position of the TriTech Institute as well as the results already achieved over this period. The timeline below highlights the key milestones from the past 18 months.



● Project Contract signed date



The TriTech Institute's position can be further described by considering the projects that it has committed to undertake to date as summarised in the table below. As illustrated, the TriTech Institute is growing a position as a leading organisation in relation to real world evaluations.

"The mission, vision and values of TriTech are aligned with those of our collaborators, and these partnerships are one of equals that focus entirely on contributing and improving the health and well-being of people in Wales."

Prof. Chris Hopkins,
Head of Innovation & TriTech Institute

Name of Evaluation/Partner	Partner Organisations	Clinical Area	Type of Study
rTMS	Life Science Hub Wales & Magstim	Mental Health	Real-world evaluation of repetitive Transcranial Magnetic Stimulation (TMS) as an alternative to electroconvulsive therapy (ECT) to treat drug resistant depression.
pH sensor and probe device for NG tube management	NGPOD & Swansea Bay	Nutrition and Dietetics	Real-world evaluation of the NGPOD device (a pH sensor and probe device) in NG tube management, as an alternative to using the current method of obtaining aspirate from the patients' NG tube then using pH test strips on the aspirate.
Transcutaneous electrical nerve stimulation for Osteoarthritis	Nurokor & UWTSD (ATiC)	Orthopaedics	Real-world evaluation of the Nurokor MiBody wearable therapy system as an adjunct to usual care for patients who have osteoarthritis of the knee and are on the waiting list for total knee arthroplasty.
Population Health Assessment, Local authority	Regional Partnership Board	N/A	The assessment will provide an overview of the population demographics and distributions across the West Wales region.
Hywel Dda UHB – TEC enabled Care – COPD	Tunstall & Delta Wellbeing	Respiratory Primary Care	To assess the implementation and economic impact of remote patient monitoring (RPM) in patients with COPD in a real-world health system.
TEC enabled Care – Heart Failure	Delta Wellbeing	Heart Failure	To assess the implementation and economic impact of remote patient monitoring (RPM) in patients with Heart Failure in a real-world health system.
TEC enabled Care – Frailty	Delta Wellbeing	Frailty Primary Care	To assess the implementation and economic impact of remote patient monitoring (RPM) in patients with Frailty in a real-world health system.
PKB	Swansea University, Pfizer, Patient	Chronic Pain	Evaluation of a new model of early intervention and management of people with persistent pain using a digital personal health record (Patient Knows Best).
Machine learning / Artificial intelligence – prostate cancer	Moondance, JIVA, Health Technology Wales	Prostate Cancer	Multimodal AI Analysis of Prostate Cancer Indicators to Reduce Patient Backlogs and Improve Patient Care.
Regulatory Medical Device Development Prototype to Clinical Testing	Corryn Biotechnologies Ltd, UK	Wound Management	Regulatory advice provided for 'electrospinning wound management device' developed by Corryn Biotechnologies Ltd, UK.
AI Falls sensor	Safehouse AI & Delta Wellbeing	Frailty	TriTech Challenge winner. Supporting testing of falls monitoring technology.
Phone Spirometry	Eupnoos	Respiratory	TriTech Challenge winner. Supporting development of phone spirometry app.
Long Covid Chat bot	Scienap	Respiratory	TriTech Challenge winner. Supporting development of Long Covid chat bot.
Wellbeing Signposting	Scienap and PocketMedic	Wellbeing	TriTech Challenge winner. Supporting development of wellbeing signposting for Hywel Dda staff.

Collaborations



Case studies:

Pioneering sensor technology aims to improve hospital efficiencies and patient outcomes in Wales. The TriTech Institute in Hywel Dda UHB, NGPOD Global Ltd, and Swansea Bay University Health Board are delivering an important service evaluation on the NGPOD testing device, which may help to improve outcomes for patients who need nasogastric feeding.

[Pioneering sensor technology aims to improve hospital efficiencies and patient outcomes in Wales | Life Sciences \(lshubwales.com\)](#)

Multimodal analysis of prostate cancer. Every year in Wales, more than 2500 men are diagnosed with prostate cancer and around 600 men die from the disease. JivaRDX is a diagnostic aid for prostate cancer that promptly highlights the existence of tumours on MRI scans. The tool enables radiologists to make more informed decisions faster. This reduces misdiagnosis, and therefore unnecessary treatment costs and complications, whilst creating better patient outcomes. Such an AI tool supports the post-COVID requirement for rapid outpatient turnaround. In this project, Prof. Chris Hopkins and Mr Sohail Moosa, working with the TriTech Institute, Hywel Dda UHB and Jiva.ai, will demonstrate the first innovative deployments of JivaRDX within NHS Wales. This project is being funded by Moondance Cancer Initiative as part of their 2021-2022 Innovation Time Awards.

[AI assisted prostate cancer diagnosis | Moondance Cancer Initiative \(moondance-cancer.wales\)](#)

Other notable collaboration success includes **Pentre Awel**, which offers the opportunity for a clinical research and delivery centre, which will enable Hywel Dda UHB to expand its research and clinical engineering provision focusing on community level clinical trials, linked to facilities on site; and provide multi-disciplinary care closer to home for a wide range of community-focused services.

Awards

MediWales, Health and Social Care Research Partnership with Industry Award.

Hywel Dda UHB's TriTech Institute and Bond Digital Health won the Health and Social Care Research Partnership with Industry Award for the development of their digital mobile phone app, COPD Pal, which allows patients to take control and manage their COPD. With funding from the Welsh Government Efficiency through Technology Programme and as part of a Bevan Commission Exemplar Project, the organisations worked collaboratively to produce a tailored prototype. Bond Digital Health then refined and added functionality to the app to ensure it met the needs of patients and clinicians. Sponsored by Health and Care Research Wales.

"The gap we've spotted is the importance of complementing the evidence relating to clinical safety and effectiveness with information on the value case for technology when positioned within a healthcare system. Healthcare systems and companies increasingly want to understand the workforce implications, costs, and outcomes delivered when a technology is introduced into a real clinical context – there's more demand for that."

Dr Leighton Phillips, Hywel Dda UHB
Director of Research, Innovation
and University Partnerships

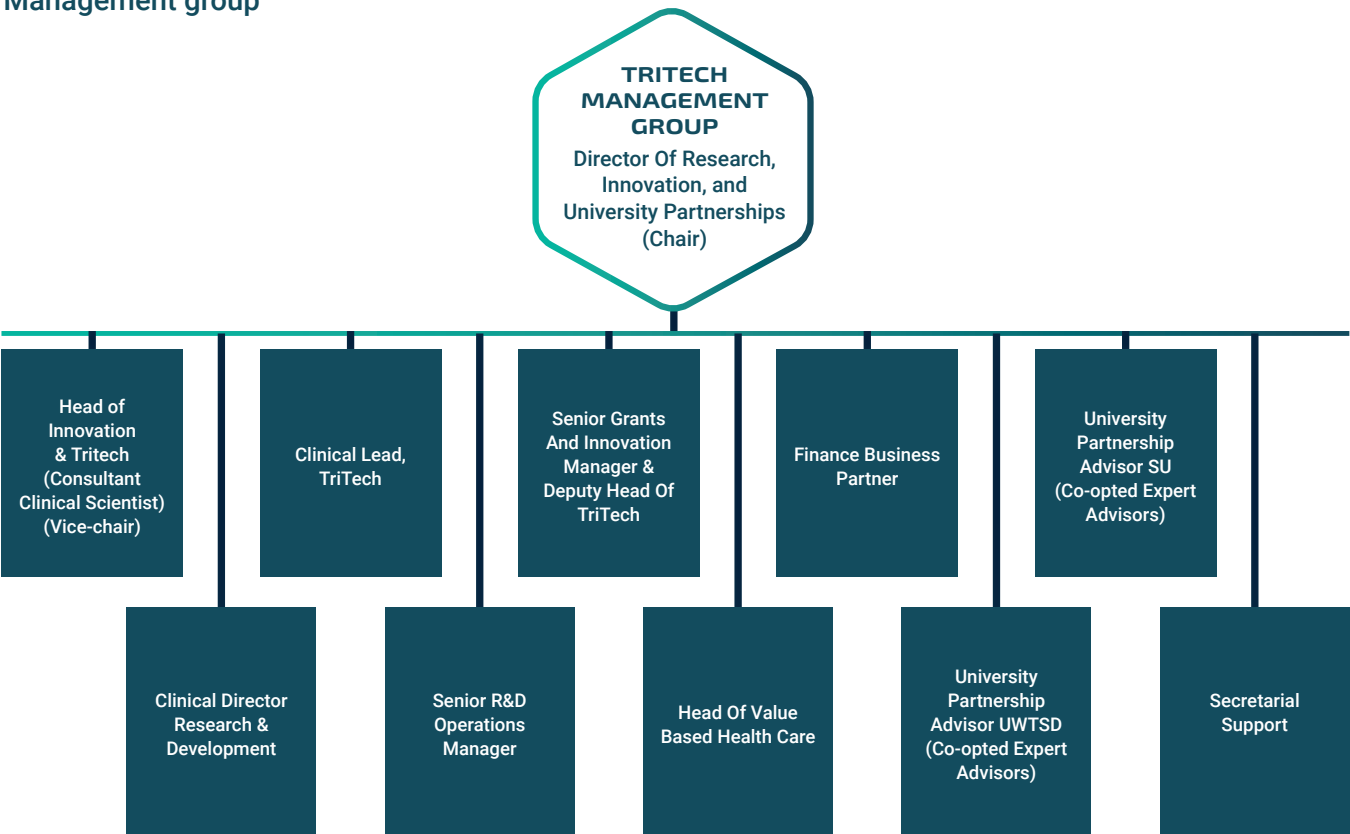


3.0 Organisation, Management Team and Governance

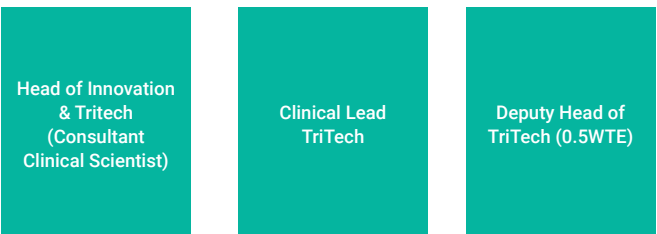
3.1 Organisation Chart

The current structure is working well and in the short term will remain as above. It will, however, be continuously reviewed as the TriTech Institute expands and grows to ensure effective succession planning team capacity, and skills to meet objectives. The TriTech Institute will continue to explore joint posts and opportunities with partner organisations, including universities and other health boards. Increasing the level of communication support will be considered during this business planning period.

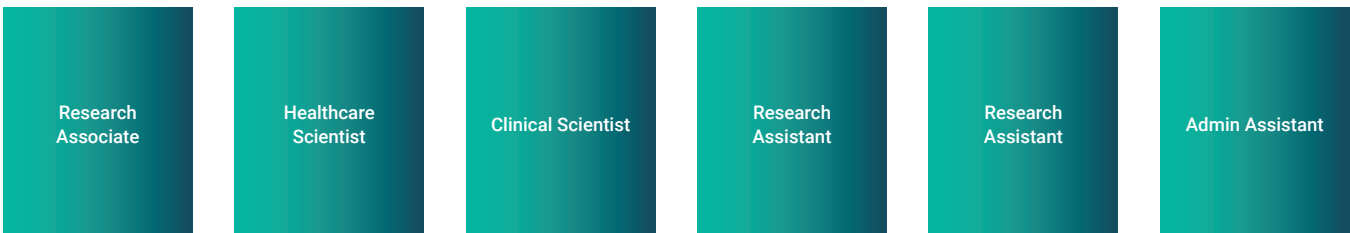
Management group



Senior team

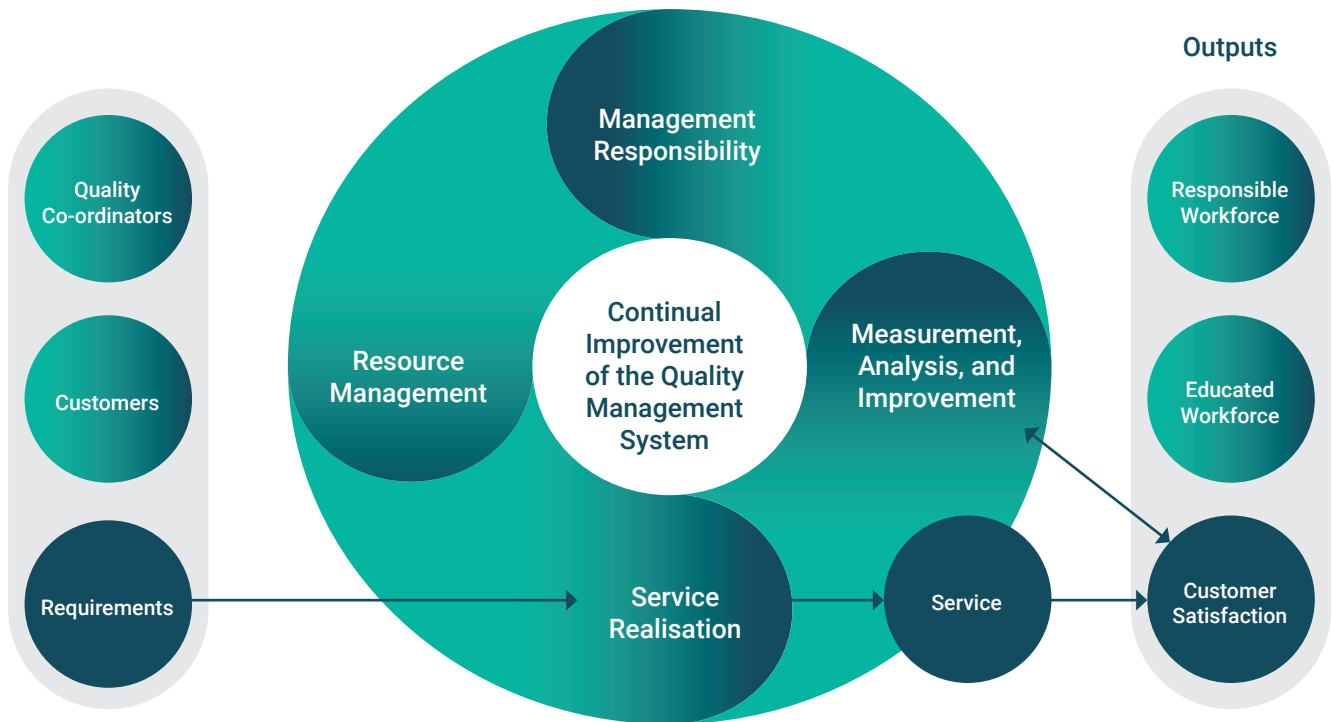


Operational team



Organisation Culture

Hywel Dda UHB has a culture of engagement, openness, and honesty and in which all elements of the workforce are encouraged to be innovative. Central to this is the need for clear and supportive leadership, including robust and empowering clinical leadership and staff engagement.



3.2 Quality and Safety Standards

The TriTech Institute has a suite of quality-related documents implemented from R&I and Clinical Engineering within Hywel Dda UHB. This includes a QMS manual currently in use within the institute that was set out to meet the needs of the international standard ISO: 13485:2016 (Medical Devices).

3.3 ISO 13485

The TriTech Institute will not advance any technology research studies within Hywel Dda UHB until its Quality Management System is in place. ISO 13485 is an international standard that sets out regulatory requirements for medical device quality management systems. ISO 13485:2021 is the 2021 amendment to the standard which comprises new annexes showing the relationship between the clauses of the standard and the requirements of the European medical devices regulations and IVD medical devices regulation. ISO 14485 is critical to the TriTech Institute being able to offer the full array of the services, notably research, that it is targeting through this business plan.

What does ISO 13485 - Medical device quality management systems cover?

ISO 13485 gives regulatory requirements for medical device quality management systems. It provides the basis for ensuring consistent design, development, production, installation, and delivery of products that are safe for their intended purpose. It also harmonizes global requirements and is recognized by regulators in many jurisdictions around the world.

Why should you use ISO 13485 - Medical device quality management systems?

ISO 13485 supports an effective medical device quality management system that consistently produces safe and effective medical devices, and demonstrates conformity with regulatory requirements. ISO 13485 further harmonizes regulatory requirements between different jurisdictions and thereby decreases the number of unique requirements for individual markets. It is an effective way to manage risk and improve processes and efficiency.

Quality Management System Manual

A suite of R&I Department Standard Operating Procedures (SOPs) were in place in regards of trials, whilst general guidance documents for government health agencies were also available.

The TriTech Institute has developed project template forms for project submissions for external companies and organisations that include information regarding device specification and regulatory marks, use of treatment type set by NICE, remits, and training required on devices or treatments.





TRITECH

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