

Name of Sub-Committee:	Research and Innovation Sub-Committee
Chair of Sub-Committee:	Dr Philip Kloer, Medical Director/Deputy Chief Executive
Reporting Period:	11 December 2023
Key Decisions and Matters Considered by the Sub-Committee:	
<p>The purpose of this report is to provide the People, Organisational Development and Culture Committee (PODCC) with an update on the Research, Innovation (including TriTech) and university partnership activities of Hywel Dda University Health Board partners, including its Research and Innovation Sub Committee (R&ISC), which met on 11 December 2023.</p> <p>1. <u>Research and Innovation Strategy</u></p> <p>The R&ISC received an update against Hywel Dda University Health Board's (HDdUHB) Planning Objective 5b, which sets out the priorities for Research and Innovation (R&I) during 2023/2024, namely delivery of the third year of the R&I Strategy (2021-24) and the third year of the five-year TriTech Business Plan. R&ISC members took assurance from the report.</p> <p>Progress against the Strategy and the associated action plan is routinely monitored and reported to the Research and Development (R&D) Leadership Group and TriTech and Innovation Group. Reports provided to these groups during the reporting period for this report described that the R&D and TriTech and Innovation Divisions are on target to deliver the objectives developed from the overarching goals within the Research and Innovation Strategy 2021-2024. Work has commenced on developing the next R&I Strategy in readiness for 2025. This will include a series of collaborative development sessions with stakeholders, staff and people participation groups and representatives and a comprehensive analysis of performance and learning points from the last four years.</p> <p>2. <u>Governance</u></p> <p>2.1 <u>Research and Development</u></p> <p><u>Health and Care Research Wales (HCRW) R&D Framework</u></p> <p>The R&D annual performance review with HCRW and Welsh Government took place on 17 October 2023 at Dura Park, during which the self-assessment of the current position against the ten pillars of the framework was discussed. The Director of Research, Innovation and Value received feedback from HCRW on the 2 November 2023. The feedback was mostly positive, with only a couple of areas for improvement. A formal response detailing an action plan was agreed by the R&ISC on 11 December 2023 and subsequently submitted to Welsh Government and HCRW on the 21 December 2023. Copies of the letters are attached at Appendix 1 and 2.</p> <p><u>Research Quality and Sponsorship Group</u></p> <p>The Research Quality and Sponsorship Group (RQSG) met on 4 December 2023 and noted and accepted the following points:</p>	

1. No new applications for research sponsorship had been made.
2. Progress was noted in relation to two existing sponsorship applications:
 - IRAS 329847 Ultrasound and Attenuation Imaging; A cross-sectional study assessing the agreement between sonographer based assessment of the fatty liver using conventional ultrasound and attenuation imaging scoring. At a Research Ethics Committee appointment on 15.11.2023, the study was considered and a favourable opinion was received on 21.11.2023, with only minor changes required.
 - IRAS 323048 FARSight-DM study – following positive internal review, study team working on minor changes to protocol before final approval from RQSG.
3. The following quality assurance points were noted: A total of 4 monitoring visits had been completed, with only minor findings, which were noted and addressed
 - IRAS 285628 - Induction of Labour study. One outstanding action remains from initial audit 20.06.23. The research Team Lead has been asked to support the Principal Investigator (PI) to complete the outstanding actions, which does not affect patient safety. The action is to amend the gaps in the enrolment log, such as missing hospital number or date of birth.
 - IRAS 295643 - Head and Neck Cancer study. This was audited on 20.06.23 and the Quality Assurance Team revisited on 25.07.23 to address outstanding actions. The Quality Assurance Team and Research Associated are supporting the PI in making sure the correct information is completed for all those recruited after 08.08.23. This does not affect data quality or patient safety. All other actions from previous report to R&ISC have now been resolved.
 - IRAS 324893 - Can left atrial strain measurements, and correlating changes in left atrium area and volume size, be used as an early predictor of atrial fibrillation? An early Monitoring visit was completed on 17.10.23. There were 5 minor findings, all of which have been addressed and the audit action plan has been closed.
 - IRAS 322107 – DIASOLE. Diasole is a hosted device study. An early study audit visit on 07.11.23 has found 8 initial findings, 3 major and 5 minor. All have been addressed and the audit is now closed.

2.2 TriTech and Innovation

Over the last reporting period to R&ISC, the TriTech and Innovation Group met twice; on the 25 September 2023 and the 27 November 2023. The following updates were received relating to governance:

- Process and Project Tracking Documentation: Trittech and Innovation have been undergoing a full review of their current process and project tracking documentation. The final version of the new combined scoping and project tracker was completed and went live on 18 September 2023 and is currently in use to track the progress on all scoping and project activities within Trittech and Innovation. With a review to be held in early 2024.
- Trittech Project documents and process: In addition to the work on the project Tracker it was decided that a new Standard operating procedure will be developed for the Trittech Institute's processes. This will include a revision of all the working project documentation within Trittech. This process will be undertaken and drafts of the documents planned for early Jan/Feb 2024.
- QUALITY MANAGEMENT SYSTEM – ISO 13485. Quality and safety standards for the Trittech Institute are part of the new ISO 13485 Quality Management System (QMS). The audit of the QMS by British Standards Institution (BSI) was subsequently undertaken between 12 and 15 September 2023 with only 3 minor findings and the QMS passed the audit.

- The TriTech and Innovation Group (TIG) and Senior Innovation and TriTech Operational Team's (SITOTs) Terms of Reference Annual Review: the terms of reference for the TIG and SITOT were both reviewed and accepted by their respective committees. Only minor changes (such as changes to the committee membership) were implemented which were brought to R&ISC (11 Dec) for decision. R&ISC members were content with the amended ToR.

University Partnerships

No meetings in respect of the governance of university partnership took place.

3. Discussion Items

3.1 Research and Development

Accommodation

R&ISC received an update on actions being taken to develop fit for purpose research facilities at Withybush Hospital (WGH). The works at WGH continue to be on-hold until essential Reinforced Autoclaved Aerated Concrete (RAAC) works have been completed. The Risk Register 1036 (RAG rated Red) reflects the risk from delay. R&ISC members noted and accepted the details within the Risk Register.

Pentre Awel Update: The R&ISC were advised that a timeframe for potential completion of Pentre Awel was awaited. It was noted by the R&ISC that the scheme is significant but the space allocated to TriTech and R&D is modest and is only possible with wider financial support of the Health Board. Progress will depend on a financial case being submitted to Board by the Executive Director of Strategy and Planning.

3.2 TriTech and Innovation

TIG and SITOT noted the following updates on evaluation services provided:

Nurokor Ltd Project: The current position for the Nurokor project is still not resolved and final payment has not been received. In collaboration with NHS Wales Shared Services Partnership (NWSSP) Legal and Risk Services (L&R), the Director for Research, Innovation and Value wrote to the CEO of Nurokor Ltd on 2 November 2023, in order to seek a resolution on the matter and a response (to date) has not been forthcoming. NWSSP L&R have now been instructed to commence proceedings against Nurokor Ltd and issue a letter in December stating their intention to take action. However, a credit report for the company undertaken by the Finance Department has found that the company already has multiple judgements against it, and a decision to pursue it for the outstanding amount would need to be weighed up against the legal costs. A decision on this matter will be taken, with the involvement of finance and legal professionals, during February 2024.

Finalised reports: Two final project reports were presented to the R&ISC, which had also been provided to the commissioning companies. The projects have been moved to 'closed' within project management documentation:

- Tunstall – To assess the implementation and economic impact of remote patient monitoring (RPM) in patients with Chronic Obstructive Pulmonary Disease (COPD) in a real-world health system.
- Llusern – An evaluation of the Llusern Point of Care Urinary Tract Infection (POC UTI) test – focus groups to understand acceptability and usability.

3.3 University Partnerships

The Director of Research, Innovation, and Value reported that meetings had taken place with each regionally based university partner and priorities agreed for 2023/24. The PODCC will receive a further update on progress against these priorities following the next round of meetings with university partners. This will support the Health Board's university status and reporting to Welsh Government.

4. Assurance Items

4.1 Research and Development

HCRW funding update

R&ISC members received a Finance update on the HCRW Research Delivery Spending Plan and R&D Investigator Accounts on 11 December 2023 and took assurance from the report. The key points included:

- **Month 8 Financial Report** – The revised Research Delivery Funding (RDF) Total for 2023/24 is £1,158,868 derived from the following:
 - £310,857 WG Grant awarded in 22/23 and deferred into 23/24 as cost recovery
 - £823,263 WG Grant Award in 23/24 (Reduced from £860,996)
 - £24,748 supplemented by Support and Delivery Centre (S&DC) hosted by Powys THB

The reduction in RDF is due to the 4% in-year cost pressure on the All Wales Research Delivery Funding.
- **Month 8 position (November)** is showing the Research Delivery Total as £13,780 overspent. This is derived from:
 - Changes in forecast due to unforeseen costs i.e., maternity leave as reported in July R&D Leadership Group, R&D Senior Team and Finance Lead have agreed to ring fence £40,000 in the Capacity Building account to reduce the funding cost pressure.
- **HCRW Month 8 position (November)** is showing the Excess Treatment Costs as £34,632 underclaimed. This is derived from the following studies:
 - CONSCOP 2 - Overestimated number of recruits
 - GBS3 - Recruitment started later than ETC start date
 - MAPS-2 - Slow recruitment
 - Assess Meso - Reduction in recruitment target figure

- **R&D Balances** – R&ISC members noted the M8 financial position for all R&D Accounts with forecast end of year balance based on current forecast formed by latest information received from respective management groups.

R&ISC members took assurance from the finance update.

Biobank

R&ISC received an update on the Biobank and noted the following the Human Tissue Authority licence has now been revoked and one final collection of samples is due to be transferred to Cardiff University in January 2024. Sam Rice (Clinical R&D Director) gave thanks to Priya Sai-Giridhar for leading this process and recognised the volume of work involved. The BioBank should be formally closed by the next R&ISC meeting (10 March 2024) and, as such, a formal close-down report will be presented. The R&ISC took assurance.

Medicines and healthcare Products Regulatory Agency (MHRA) Inspection Ready Project

The R&ISC received an update on the MHRA Inspection Ready Project and noted the intention was to ensure that the Departmental arrangements ensure the high quality conduct of research were in place and to a similar standard that would be required by an MHRA inspection. The report provided an update and reassurance that the project would be completed by the next R&ISC. The R&ISC took assurance from the report.

Freezer On-Call

The R&ISC committee received a report on changes to the Freezer On-Call. With a reduction in HCRW delivery funding HDdUHB were asked by HCRW to review all non-pay costs currently submitted as part of the annual spending plan. Freezer on-call costs represent the highest proportion of current costs therefore a decision to relocate the –80 degree freezers currently positioned in Glangwili Hospital Clinical Research Centre (CRC) and Prince Philip Hospital (PPH) CRC into the pathology laboratories was agreed and as a consequence the costs associated with R&D staff providing a freezer on-call rota would cease. The Organisational Change Process (OCP) is ongoing, with a cost-saving due to be seen in 2024/2025 as requested by HCRW. Provision has been made for the air conditioning (A/C) in the lab in PPH to be upgraded if required and the temperature of the freezer is currently being monitored to assess. If the temperature cannot remain within range during the summer months, A/C may be required. These costs will be discussed with HCRW, taking into account the saving from ceasing the on-call system.

R&ISC members took assurance from the report.

4.2 TriTech and Innovation

TriTech and Innovation Finance Update

The R&ISC received and were assured with an update on the financial position of the TriTech and Innovation Division. The key points were:

- **Financial Update:** In 2023/24, financial performance is being monitored monthly through a financial tracker, a summary of which is included. The tracker also monitors performance of

each individual project to ensure costs do not exceed funding. M6 Report 2023/24 – Month 6 position (end of September 2023) is showing a forecast end of year balance as £64,973k underspend. The underspend in month is mainly attributable to grants being awarded in full in advance of spend against the relevant projects. All grant income is fully committed, and the underspend is deferred into the next reporting period. The TriTech Business Plan forecasted return of £84,694 for 23/24, therefore the M6 forecast is £20,000 adrift of the end of year target. R&ISC members took assurance from the finance update.

- **TriTech Key Performance Indicators (KPI(s)) report:** A separate KPI report was taken to PODCC on 17 August 2023 and, whilst positive, some considerations and issues were raised by PODCC. PODCC asked that the current KPI tracker was revised as it was currently hard to track progress and it was asked that the language used in some of the descriptions and deliverables of the KPIs should be reviewed. In response, a new KPI Tracker has been completed and been reviewed at the TIG on 25 September 2023. R&ISC took assurance from the revised KPI tracker and were content that it be presented to PODCC (Appendix 3).

4.3 University Partnerships

Nothing to report.

5. Information Items

5.1 Research and Development

R&ISC received an update on key performance and operational matters facing the Division, including:

Performance Key Indicators for HCRW are on target:

‘Research to Time and Target’ (RTT) is a key indicator of performance and relates to individual studies achieving the number of expected recruited patients over the period of study (or pro-rata for open studies). The percentage shown is the proportion of studies achieving RTT (commercial and non-commercial studies are considered separately). In order to have local autonomy with our budget, the 6 month rolling data of RTT for closed non-commercial studies needs to be at least 70% of studies achieving their target recruitment.

- Recruitment to Time and Target is currently at 100%, which is a great achievement and shows an appropriate portfolio for the demographic.
- RTT – 6 month rolling trend data for closed non-commercial portfolio studies = 100%
- Data completeness is 98%

Committee noted that performance is positive and HDdUHB are currently the third highest non-commercial study patient recruiter in Wales. It was noted that there is continued effort to increase commercial portfolio as this remains a focus for improving financial security. Committee members took assurance from the report.

5.2 TriTech and Innovation

National Botanic Garden of Wales - Shades of Green Partnership Project

The Director of Research, Innovation and Value provided a verbal update on a partnership with the National Botanical Gardens. He explained that he has been supporting a Senior One Health Practitioner (SOHP) with this biophilic project. Biophilic design is concerned with the design of public buildings and ways to incorporate green, such as the new Alder Hay Hospital. It is not without challenge to make a case for biophilic design in the current constrained financial climate, but practical opportunities have been determined. Grants have been applied for and the bid for work with the Botanical Gardens Wales was successful and is looking at building community gardens. This is a positive step to reconnect people with nature.

The Director explained that there is no single committee to present this report to, but it is innovative so fits in with the remit of this group. The project lead has been engaging with many internal teams and also externally across the Third sector. The R&ISC noted the project and welcomed the opportunity for ongoing updates.

5.3 University Partnerships

R&ISC were reminded of the formal partnership with the three universities (University of Wales Trinity Saint David (UWTSD), Swansea University and Aberystwyth University). Every year HDdUHB meets with each university to plan the next year, then meeting twice throughout the year to review progress. A more in-depth update will be given in the March 2024 R&ISC as the annual review will have taken place.

The committee member from UWTSD gave a verbal update. Work is going well with the ATiC/TriTech collaboration and further collaborations with Life Science Hub Wales and TriTech are being considered. Applications for UK Research and Innovation (UKRI) bids are currently at a 50% success rate, which is very positive. UKRI is a non-departmental public body sponsored by the Department for Science, Innovation and Technology (DSIT) who offer funding for various organisations, including NHS bodies and researchers. For the Pentre Awel project ATiC are collaborating with TriTech and conversations are taking place with the Board.

The committee member for Aberystwyth University gave a verbal update. The recent success of the £1m Innovate UK bid involving the Health Board and other organisations to diagnose Lung Cancer was highlighted.

Matters Requiring People Planning and Performance Assurance Committee Level Consideration or Approval:

The People, Organisational Development and Culture Committee are asked to:

- Take assurance from Research & Development (R&D), TriTech & Innovation Group (TIG) and University Partnership activities and decisions reported.

Risks / Matters of Concern:

Changes Since Previous Report (September 2023)

Total Number of Risks	3
New risks	0
Closed/Archived risks	0
No change in risk score →	3
Increase in risk score ↑	0
Reduction in risk score ↓	0
Risks overdue for review	0

Risk Reference and Title	Date Risk Identified	Executive Director	Current Risk Score	Update	Target Risk Score
1492 – Research delivery funding (Service Level) <i>This risk is currently being 'Tolerated'.</i>	29/09 /2022	Dr Philip Kloer	3x3=9 à (reviewed 24/11/23)	The annual spending plan for 23/24 was confirmed by HCRW at the end of May 2023, any adjustments to staffing will be negotiated on a 'needs basis' following the Research Delivery Funding Decision Framework published by HCRW. A 4.7% cost recovery target is in progress for 2023/2024.	3x1=3
1036 – Lack of research facilities in <u>Withybush</u> Hospital (Service Level)	26/05 /2016	Dr Philip Kloer	4x3=12 à (reviewed 24/11/23)	Space identified in WGH on the ground floor behind the laboratories has been confirmed but the timeline for relocation is uncertain. Update from WH is that works commence on 11 March 2024, with target completion within 20 weeks.	3x1=3
1160 – Lack of research leadership (Directorate Level)	07/08 /2018	Dr Philip Kloer	3x3=9 à (reviewed 24/11/23)	In May 2023, the Likelihood score was reduced in view of increased numbers of staff with research leader time awards.	3x2=6

R&ISC received the R&D risk update on 11 December, and the Committee noted and accepted the report based on the revised scores to risk 1036 in light of the RAAC situation at WGH.

TriTech & Innovation risk:

Total Number of Risks	5
New risks	0
Closed/Archived risks	
No change in risk score →	5
Increase in risk score ↑	0
Reduction in risk score ↓	0

Risk Reference and Title	Date Risk Identified	Executive Director	Current Risk Score	Update
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1511 – The risk that the regulatory climate may impact on opportunities to innovate	31/08/2022	Professor Philip Kloer	3x2=6 → (reviewed 23/08/23)	<p>Actions can only expect to reduce the impact of the risk. As ISO13485 is an international standard, successful certification reduces the impact that changes in national regulatory framework could have.</p> <p>We have to assume the likelihood is low as the government is unlikely to change regulations that will affect medical device innovation in the UK.</p>
1510 – Timely Delivery of Project Outputs	31/08/2022	Professor Philip Kloer	3x2=6 → (reviewed 23/08/23)	<p>Most projects carried out to date have been delivered on time and the only exception to this, which was delivered late, the company was satisfied and no issues arose. No customer complaints have been received to date.</p> <p>The risk remains open as reputational damage could impact on the financial risk, staff recruitment and retention and other projects.</p>
1509 – The risk of competitors developing a similar model to TriTech	31/08/2022	Professor Philip Kloer	2x3=6 → (reviewed 23/08/23)	<p>It is difficult to prevent emerging competitors, but the impact of competitors can be reduced by maintaining a competitive advantage. There is potential for other Health Boards to adopt the TriTech model.</p> <p>In 2023, TriTech has been considering working with other health boards across Wales to help them develop in collaboration with HDdUHB rather than against us to adopt the TriTech model.</p>
1508 – The risk of a lack of clinical leadership to support TriTech projects	31/08/2022	Professor Philip Kloer	3x2=6 → (reviewed 23/08/23)	<p>No issues have arisen thus far in identifying clinical leads to take on research or evaluation projects.</p> <p>For TriTech to effectively increase the number of projects, an increase in the number of clinical leads able to take on clinical investigations or evaluations is also required.</p> <p>This risk remains open as there is the potential for an increase in risk score in the future.</p>
1507 – TriTech and	01/04/2022	Professor Philip Kloer	4x1=4 →	<p>Current demand for services is sufficient to meet income generation targets with</p>

Innovation: Financial Delivery Year 3			(reviewed 23/08/23)	positive forecasts as outlined in the business plan. Monthly finance tracker is monitored with Finance business partners. Multiple measures are in place to increase exposure and reputation of TriTech Institute towards potential commercial partners. Year 3 target has already been completed as of April 2023. This year, the focus is to build up surplus for Year 4 targets. Monthly finance tracker is monitored with Finance business partners. Multiple measures are in place to increase exposure and reputation of TriTech Institute towards potential commercial partners.
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Since the previous PODCC report, there have been no changes to the TriTech Risk Register. The R&ISC noted and accepted this update.

Planned Sub-Committee Business for the Next Reporting Period:

Future Reporting:

- RESEARCH & DEVELOPMENT– Quality, Performance & Finance
- R&D Team Activity Report
- R&D Performance
- R&D Risk Register
- R&D Governance from RQSG
- R&D Financial Report
- HCRW / National Developments
- Any Other R&D Papers
- INNOVATION – Strategy & Progress Report
- TriTech & Innovation Activity Report
- TriTech Risk Register
- TriTech Financial Report
- National Developments
- Any Other Innovation Papers
- Reports on Strategy Progress
- Strategy Action Plan for 23/24 & progress report
- Update from Partnership Meetings

Date of Next Meeting:

11 March 2024

**Feedback from the annual review meeting between Health and Care Research
Wales and Hywel Dda UHB**

2 November 2023

Dear Leighton and Phil,

Thank you for meeting with me and my colleagues from Health and Care Research Wales (HCRW) as part of the annual review process to discuss how health and care research and development in Hywel Dda University Health Board (HDUHB) is progressing.

As outlined, the purpose of the meeting was to have a structured and mutual dialogue, to discuss and agree between yourselves and HCRW what is working well within HDUHB and to identify actions that need to be taken to improve health and care research across the Board. We used the recently published Welsh Government NHS R&D Framework and your completed assessment template, alongside data for all Health Boards and Trusts previously circulated on HCRW Faculty awards and membership; research delivery funding and activity; and HCRW research project funding scheme applications and awards.

We felt it was a really constructive meeting, and I am writing to provide some feedback and to propose some next steps. Those present at the meeting are listed at the bottom of this letter.

1. We discussed your R&I strategy and the meaningful stakeholder activity and peer review which led to its development, and we felt that it was a really thoughtful and detailed document. With regard to implementation, there were strong governance and monitoring processes in place via the People, Organisation Development and Culture Committee (PODCC) and the Research and Innovation Sub Committee (R&ISC), and these committees are engaged in the research agenda and meet regularly.
2. In discussing the profile of R&D at Executive Board, we noted that you have held a board development day on R&D, have strong relationships with your colleagues covering value based healthcare to integrate research into a

broader agenda and also use the board's Datix management system to report risks to support resolving issues such as the lack of research facilities and lack of protected time for staff, which has been an effective mechanism to also raise the profile and impact of research. You mentioned that you will be refreshing your R&D strategy as the current version covering 3 years from 2021 will soon run out and that provides you with an opportunity to reflect on your successes, what has worked well and also to ensure the next version has strong alignment with the NHS R&D Framework in areas where you have gaps.

3. We also discussed engagement across the clinical directorates across the DGHs and you recognised that there is not a formal mechanism to do this and that it is variable – understanding that there are challenges with geography. Again, using the NHS R&D framework as a platform for wider discussions as well as using your existing networks of lead nurses could provide an opportunity to think about whether you have the right strategy in place to ensure that research has visibility across the organisation.
4. We heard about the working relationships and engagement with academia, and how the previous University Partnership Board has been replaced by bilateral meetings between the Health Board and each of the Universities (Swansea, Aberystwyth, and University of Wales Trinity St David's) which have proved more beneficial and led to wider conversations in non-medical areas and joint appointments via TriTech. Having strong partnerships with academia is a key part of developing the workforce therefore you may wish to think about how the strategic alignment of priorities could facilitate further joint appointments between your organisations and respective HEIs, and explore rejuvenating relationships in rural health which is a pertinent due to the geography of the Health Board.
5. We were pleased to hear that there is commitment from the Health Board to continue funding for those who have successfully been awarded a HCRW Research Time Award and that the Health Board is also focusing on staff from non-medical backgrounds, although you acknowledged this is an area that is underdeveloped. There is opportunity now to evolve a research workforce strategy and increase engagement with the HCRW Faculty, and working with the Director of Faculty we have agreed that a next step would be to establish a regional workshop to motivate those with an interest in research and explore how the HCRW Senior Research Leaders can be used to support research interested staff.
6. The work the Health Board has done to facilitate access to studies for Hywel Dda patients and the development of smooth patient pathways was recognised, with established sites for recruitment in three of the Health Board's four hospitals. The challenges of Health Board patients accessing oncology studies that are being led in Swansea Bay UHB was discussed which is contrary to the existing regionalised service model for oncology. Currently this inequitable clinical trial activity is not sustainable or fair, and you advised that resolution of this is a key priority for Hywel Dda UHB. The reasons behind this are not clear, and you suggested that appointing a regional delivery manager could provide a solution, as well as aligning with the national - CREST strategy. HCRW agreed (via the Director of Support and Delivery) to facilitate and support discussions between Hywel Dda and Swansea Bay University Health Boards.

7. We noted the lack of commercial research activity at Hywel Dda UHB and discussed the possible reasons for this. You advised that this is related to having only small pockets of interest across the organisation (i.e. respiratory) and having less experienced clinicians. Capacity and capability issues and the geographical operational challenges of having cross cover across the sites is also an issue for commercial studies and this is something that the R&D team are mindful of, and it is hoped that the growth of the commercial portfolio is something that will happen in slower time. A Once for Wales approach, using the Moderna and BioNTech Strategic Partnership was acknowledged as assisting here as well as establishing a relationship with Swansea Bay UHB to grow commercial research is something that is needed, and that will unlock the gateway and relationship to commercial companies. Swansea Bay UHB needs to have an interest in Moderna and BioNTech to enable Hywel Dda UHB to participate.
8. Your self-assessment was candid about the need for more Patient and Public Involvement (PPI) support and expertise to improve your practice in this area especially with regards the National Standards on Public Involvement and expanding your engagement with more diverse communities. It was great to hear about positive research news stories and the ambassadors you have for research in Hywel Dda UHB so please also keep sharing them with us so we can highlight more widely. We also discussed the value of more creative internal communications to raise awareness of research with all staff and how to get visibility and 'cut through' for research at the main Board. We would be happy to support you with PPI and strategic comms and value the representation you regularly have on our national Alliances.

We hope you find this feedback helpful, and I and colleagues would be happy to discuss and clarify any points we have made. We recommend that you share this feedback with everyone who attended the meeting or was invited to do so; with your board; and with other relevant colleagues in the organisation. It would be helpful if you could respond to this letter in due course with a brief note of actions that you plan to take – though this could of course be incorporated into a wider implementation plan.

As we mentioned in the meeting, we want the implementation of the NHS R&D Framework to support ongoing improvement in health and care research and development across Wales. To this end, once we have completed all board and trust reviews we will produce a summary document of common themes and findings and we will work with R&D directors and other stakeholders on what we can do to help share good practice and continue to raise the profile of research and development.

Best wishes



Professor Kieran Walshe
Director, Health and Care Research Wales

Attendees	
Phil Kloer	Medical Director, Hywel Dda University Health Board
Leighton Phillips	Director, Research Innovation & Value, Hywel Dda University Health Board
Sam Rice	Clinical Director, Hywel Dda University Health Board
Sally Hore	Head of R&D, Hywel Dda University Health Board
Jennifer Thomas	Senior Finance Business Partner, Hywel Dda University Health Board
Professor Kieran Walshe	Director of Health and Care Research Wales
Carys Thomas	Head of R&D Policy, Research and Development Division, Welsh Government
Monica Busse	Director of the Health and Care Research Wales Faculty
Nicola Williams	Director of Support and Delivery, Health and Care Research Wales
Helen Grindell	Deputy Director of Support and Delivery, Health and Care Research Wales
Felicity Waters	Head of Communications, Engagement and Involvement, Health and Care Research Wales
Claire Bond	Senior Funding and Performance Manager, Research and Development Division, Welsh Government



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Dear Kieran,

Annual Performance Review Meeting

Thank you for visiting Hywel Dda University Health Board (UHB) on 17 October 2023, as part of the annual Research and Development review process, and for your feedback letter dated 2 November 2023. We found the meeting constructive. The feedback will enable us to plan and prioritise our actions moving forward. As requested, please see our response to the issues raised within your letter.

1. Your Feedback: We discussed your R&I strategy and the meaningful stakeholder activity and peer review which led to its development, and we felt that it was a really thoughtful and detailed document. With regard to implementation, there were strong governance and monitoring processes in place via the People, Organisation Development and Culture Committee (PODCC) and the Research and Innovation Sub Committee (R&ISC), and these committees are engaged in the research agenda and meet regularly.

Our Response: We will continue to ensure there are strong governance and monitoring processes in place. As an example of our commitment to strong governance, we shared our self-assessment and your feedback letter at the Research and Innovation Sub Committee on 11 December, together with an improvement plan. This will now be considered by the parent Committee and full Health Board.

2. Your Feedback: In discussing the profile of R&D at Executive Board, we noted that you have held a board development day on R&D, have strong relationships with your colleagues covering value based healthcare to integrate research into a broader agenda and also use the board's Datix management system to report risks to support resolving issues such as the lack of research facilities and lack of protected time for staff, which has been an effective mechanism to also raise the profile and impact of research. You mentioned that you will be refreshing your R&D strategy as the current version covering 3 years from 2021 will soon run out and that provides you with an opportunity to reflect on your successes, what has worked well and to ensure the next version has strong

alignment with the NHS R&D Framework in areas where you have gaps.

Our Response: We plan to start working on the next iteration of the R&D Strategy 2025- 2029 early next year and will utilise the recently published Welsh Government NHS R&D Framework and self-assessment feedback to help focus on areas for improvement and prioritisation. We can share at this point that commercial research, oncology trials, and strengthening our development capacity will be priorities.

3. Your Feedback: We also discussed engagement across the clinical directorates across the DGHs and you recognised that there is not a formal mechanism to do this and that it is variable – understanding that there are challenges with geography. Again, using the NHS R&D framework as a platform for wider discussions as well as using your existing networks of lead nurses could provide an opportunity to think about whether you have the right strategy in place to ensure that research has visibility across the organisation.

Our Response: We are aware that both our internal and external communication strategies and infrastructure need continuous enhancement, to ensure we maintain a presence and increase our visibility within and outside the organisation. We will work with our 'site based' research leads to develop an approach in the context of our new strategy. We will continue to work with our leading investigators across the organisation, to ensure they are sharing the opportunities and challenges associated with their work with their departmental leadership arrangements.

4. Your Feedback: We heard about the working relationships and engagement with academia, and how the previous University Partnership Board has been replaced by bilateral meetings between the Health Board and each of the Universities (Swansea, Aberystwyth, and University of Wales Trinity St David's), which have proved more beneficial and led to wider conversations in non-medical areas and joint appointments via TriTech. Having strong partnerships with academia is a key part of developing the workforce therefore you may wish to think about how the strategic alignment of priorities could facilitate further joint appointments between your organisations and respective HEIs and explore rejuvenating relationships in rural health which is a pertinent due to the geography of the Health Board.

Our Response: We continue to explore collaborative opportunities with all our university partners. Focusing our priorities with each organisation through objectives underpinning our strategic priorities within R&D, Innovation, VBHC and workforce has been valuable this year. We note your observations regarding rural health research and will meet with Rural Health and Care Wales and the Centre for Rural Health Research in Aberystwyth University to consider the additional action we could take. Linked to this, we will also meet Professor Andrew Carson-Stevens to identify further steps we could take to build our primary care research portfolio, with an initial focus on Ceredigion.

5. Your Feedback: We were pleased to hear that there is commitment from the Health Board to continue funding for those who have successfully been awarded a HCRW Research Time Award and that the Health Board is also focusing on staff from non-medical backgrounds, although you acknowledged this is an area that is underdeveloped. There is opportunity now to evolve a research workforce strategy and increase engagement with the HCRW Faculty, and working with the Director of Faculty we have agreed that a next step would be to establish a regional workshop to motivate those with an interest in research and explore how the HCRW Senior Research Leaders can be used to support research interested staff.

Our Response: The Director of Research, Innovation and Value is supporting several of the HCRW Faculty programmes as an assessor. We will continue using the job planning and induction

processes to help identify research-interested clinicians from all clinical backgrounds. We will arrange a regional workshop with the HCRW Faculty Director early in 2024 to promote and disseminate wider research opportunities within the Health Board. We consider there to be a fine line between 'development' and 'delivery' activities (i.e., without the development of competent principal and chief investigators, it is not possible to deliver studies) and there is a need for an ongoing discussion with Welsh Government and HCRW about how we locally support the former.

6. Your Feedback: The work the Health Board has done to facilitate access to studies for Hywel Dda patients and the development of smooth patient pathways was recognised, with established sites for recruitment in three of the Health Board's four hospitals. The challenges of Health Board patients accessing oncology studies that are being led in Swansea Bay UHB was discussed which is contrary to the existing regionalised service model for oncology. Currently this inequitable clinical trial activity is not sustainable or fair, and you advised that resolution of this is a key priority for Hywel Dda UHB. The reasons behind this are not clear, and you suggested that appointing a regional delivery manager could provide a solution, as well as aligning with the national - CREST strategy. HCRW agreed (via the Director of Support and Delivery) to facilitate and support discussions between Hywel Dda and Swansea Bay University Health Boards.

Our Response: The access to oncology studies for our patients continues to be one of our strategic priorities and we are working hard with our colleagues in Swansea Bay UHB and HCRW to understand and find solutions to study specific issues as they arise. Some good recent examples are the PICCOS and BRIOCHe studies. Our plan is to continue identifying and overcoming potential and actual barriers to the adoption of a more regional approach to oncology research, acknowledging some very real constraints in the capacity and capability of the research delivery staff and support teams and the differences in structure, funding, and working practices between both organisations. We will engage with your proposed facilitation of discussions on this issue.

7. Your Feedback: We noted the lack of commercial research activity at Hywel Dda UHB and discussed the possible reasons for this. You advised that this related to having only small pockets of interest across the organisation (i.e. respiratory) and having less experienced clinicians. Capacity and capability issues and the geographical operational challenges of having cross cover across the sites is also an issue for commercial studies and this is something that the R&D team are mindful of, and it is hoped that the growth of the commercial portfolio is something that will happen in slower time. A Once for Wales approach, using the Moderna and BioNTech Strategic Partnership was acknowledged as assisting here as well as establishing a relationship with Swansea Bay UHB to grow commercial research is something that is needed, and that will unlock the gateway and relationship to commercial companies. Swansea Bay UHB needs to have an interest in Moderna and BioNTech to enable Hywel Dda UHB to participate.

Our Response: The issues behind our lower levels of commercial research require further analysis. We would ask for one correction to your feedback. Our clinicians are experienced but may be less interested and experienced in the conduct of commercial trials. As you are aware, the Director of Research, Innovation, and Value has been part of the Clinical Research Delivery Review Group led by Professor Tom Walley. The Review includes a consideration of commercial research delivery and we will use its findings to inform the approach within Hywel Dda UHB. In the meantime, we are working to overcome known constraints, including protecting the time of investigators, putting in place the wider organisational support (e.g. pharmacy and radiology), and building the confidence and capability of our R&D support and delivery team. Also, we have opened discussions with the Joint Clinical Research Facility (JCRF) team at Swansea University to identify whether there are collaborative working opportunities.

8. Your Feedback: Your self-assessment was candid about the need for more Patient and Public Involvement (PPI) support and expertise to improve your practice in this area especially with regards the National Standards on Public Involvement and expanding your engagement with more diverse communities. It was great to hear about positive research news stories and the ambassadors you have for research in Hywel Dda UHB so please also keep sharing them with us so we can highlight more widely. We also discussed the value of more creative internal communications to raise awareness of research with all staff and how to get visibility and 'cut through' for research at the main Board. We would be happy to support you with PPI and strategic comms and value the representation you regularly have on our national Alliances.

Our Response: We plan to link more closely with the HCRW PPI Team and utilise their expertise and extensive network to increase meaningful PPI engagement going forward. We are aware we have some further work to do to increase both our internal and external presence; we will use our existing links with the communications team at HCRW to increase our visibility. We plan to refresh and relaunch our R&I Newsletter in the New Year.

We look forward to working with you and the wider HCRW team over the forthcoming year.

Best wishes.



Leighton Phillips
Director, Research, Innovation and Value



Phil Kloer
Medical Director & Deputy CEO

TriTech Institute & Innovation

Progress against business plan key performance indicators (KPI's)

(23 January 2024)

No.	Description	Current Position	Confidence Level to achieve / maintain set target
KPI 1	On-time delivery of projects		
KPI 2	Incidents & complaints		
KPI 3	Non-conforming events		
KPI 4	Income generation		
KPI 5	Effective governance		
KPI 6	Clinical leadership		
KPI 7	Academic collaborators		
KPI 8	Publications		
KPI 9	Intellectual Property (IP)		
KPI 10	Grant income		
KPI 11	Local economic growth		
Date: 16/1/24			

Key	
Red	Area of concern, unmet KPI or likelihood is that KPI will not be met.
Amber	Progress in achieving KPI below expected level or issue/s raised that have potential to hamper reaching desired level.
Green	KPI has been met, on target or confidence can be taken that KPI will be achieved and/or maintained.

KPI 1 On-time delivery of projects

No	Objective	KPI Descriptor	Rationale	Measure	Frequency & Mechanism
1	Ensure on time delivery of project contract deliverables.	Effective delivery of signed contract.	Maintaining reputation, trust, return business & income.	100% of contract deliverables achieved.	Bi-monthly through TriTech & Innovation Group.

TI & I Year		No. of Projects Completed	Projects Completed on Time		Comment
			No.	%	
1	2021-22	2	2	100%	
2	2022-23	11	11	100%	Updated figures.
3	2023-24	4	4	100%	As of December 2023
4	2024-25				
5	2025-26				
Confidence Level.		All current projects on schedule to be completed by due date.			By: SMF Date: 16/1/24
Data not available		Data Source: KPI Source Info			

KPI 2 Incidents and complaints

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
2	To address all incidents & complaints in a timely manner.	Incidents & complaints are acted upon in a timely manner.	Datix incidents & complaints are investigated and managed through the Quality Management System (QMS).	100% investigated & acted upon appropriately within 30 days.	No incidents or complaints received in 2021-22.	Regularly through the QMS review meetings.

TI & I Year		No. of Incidents & Customer Complaints	Investigated & Acted upon		Comment
			No.	%	
1	2021-22	0	n/a		None recorded
2	2022-23	0	n/a		None recorded
3	2023-24	0	n/a		None recorded as of December 2023
4	2024-25	0			
5	2025-26	0			
Confidence Level.					By: SMF Date: 16/1/24
Data not available		Data Source: QMS meetings			

KPI 3 Non-conforming events

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
3	To reduce non-conforming events involving QMS processes and supporting documentation.	Any non-conforming events are acted upon promptly.	This is a QMS requirement in order to maintain registration to ISO13485.	100% investigated and acted upon appropriately within 60 days.	No non-conforming events in 2021-22.	Regularly through the QMS review meetings.

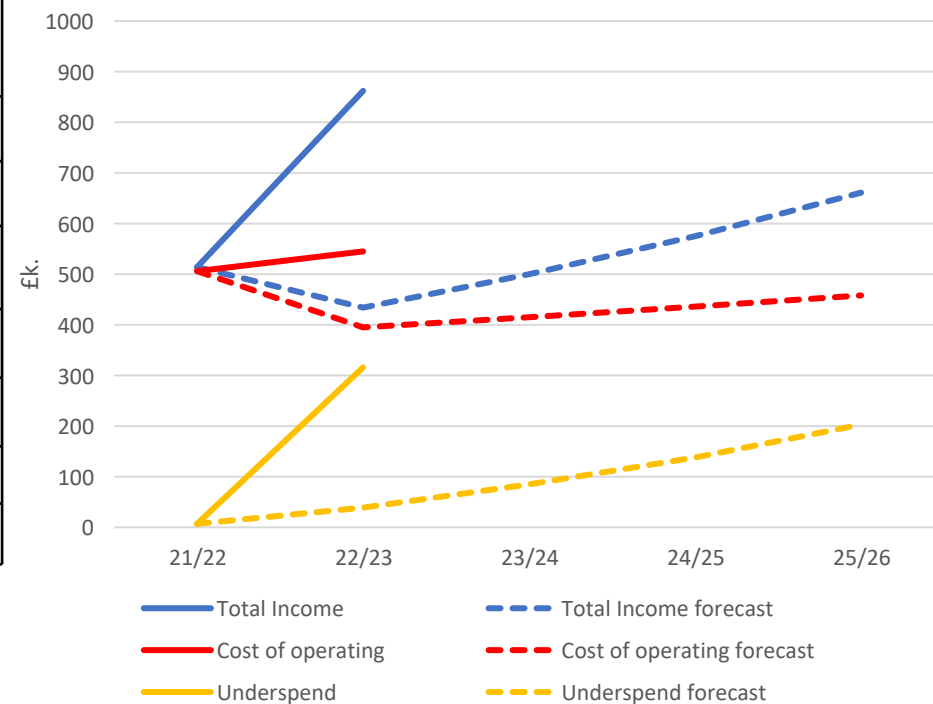
TI & I Year		No. non-conforming events	Events acted upon		Comment
			No.	%	
1	2021-22	0	n/a		None recorded
2	2022-23	0	n/a		None recorded
3	2023-24	3	n/a		3 x minor non-conforming events highlighted during BSI audit (Sept 2023) – all relating to Clinical Engineering activities outside scope of TI&I.
4	2024-25				
5	2025-26				
Confidence Level.					By: SMF Date: 16/1/24
Data not available		Data Source: QMS audit & meetings			

KPI 4 Income generation

No	Objective	KPI Descriptor	Rationale	Measure	Frequency & Mechanism
4	Ensuring annual income generated achieves targets set within business plan (June 2022).	Generating sufficient income.	Supports the financial position of TI&I.	Annual income measured against target within TI&I business plan.	Annually

TI & I Year	Cost of Operating (£k)	Total Income Generated (£k)	Under spend (£k)	Comment
1 2021-22	£506*	£513*	£7	As previously reported
2 2022-23	£545*	£862*	£316	As reported to TIG April 2023
3 2023-24	£415**	£500**	£85**	For completion using data supplied by financial business partners – by May 2024.
4 2024-25	£436**	£575**	£139**	
5 2025-26	£458**	£661**	£203**	
Confidence Level.				By: SMF Date: 8/9/23
Data not available	Data Source: *Finance Tracker **TriTech Business Plan Target (June '22)			

Target income / Income generated / Underspend



KPI 5 Effective governance

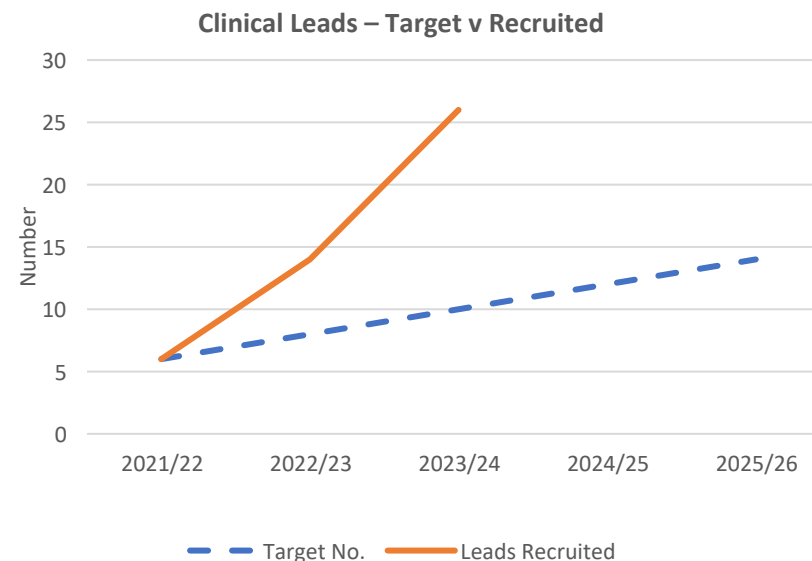
No5	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
5	Ensure TI&I is governed effectively & its activities are of a high standard.	QMS in place supported by suite of Standard Operating Procedures.	UK regulatory requirement for all new clinical investigations on medical devices. Ensures TI&I is governed effectively & provides quality assurance on projects undertaken.	Development & adoption of internal SOPs. Demonstration through (NWSSP) audit, adherence to HDUHB corporate governance policies & procedures. Achieve & maintain certification to ISO13485 through periodic external audit (BSI).	Baseline audit May 2022.	Annually

TI & I Year		Accreditation Status	Comment
1	2021-22		<ul style="list-style-type: none"> Baseline audit May 2022 Development of QMS documentation for newly formed TriTech Institute.
2	2022-23	Certification achieved.	Certification to ISO13485 (7.3 Design) November 2022
3	2023-24	Certification renewed.	Sept '23 – surveillance audit passed – 3 minor NCRS raised all relating to activities undertaken solely by Clinical Engineering.
4	2024-25		Re-certification audit – anticipated approx. August 2024.
5	2025-26		
Confidence Level.			By: SMF Date: 22/11/23
Data not available or n/a			Data Source: QMS meetings

KPI 6 Clinical leadership

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
6	Increase the number of clinicians capable of leading TI&I projects.	Number of clinicians willing and capable of supporting TI&I projects.	TI&I can only take on research & evaluation projects with the support and contribution of clinical colleagues.	Increase the number of clinical leads by 2 per year.	6 clinical leads recruited in 2021-22.	Annually

TI & I Year	Target No. of Clinical Leads	No. of Clinical Leads	Comment
1 2021-22		6	Baseline position
2 2022-23	8	14	As reported to TIG April 2023
3 2023-24	10	26	As of December 2023
4 2024-25	12		
5 2025-26	14		
Confidence Level.			By: SMF Date: 16/1/24
Data not available			Data Source: TI&I SharePoint



KPI 7 Academic collaborations

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
7	Increase the number of formal project collaborations with universities & other organisations (e.g. charities).	Number of project collaborations.	Working with universities (& others) improves the skill mix and capabilities of TI&I, enabling it to undertake a larger number of projects & secure greater impact.	Embark on 1 additional project collaboration per year.	Two collaborative projects in 2021-22.	Annually.

TI & I Year		Target for the no. Collaboration Projects	No. of Collaborative Projects	Comment
1	2021-22		2	Baseline position
2	2022-23	3	4	As reported to TIG April 2023
3	2023-24	4	5	As of December 2023
4	2024-25	5		
5	2025-26	6		
Confidence Level.				By: SMF Date: 16/1/24
Data not available		Data Source: KPI Source Info.		

KPI 8 Dissemination Activities

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
8	Increase the dissemination of project findings and TI&I activities.	Number of publications, posters and conference presentations as a consequence of projects and activities undertaken by TI&I.	Securing wider dissemination of findings supports confidence, impact, and in so doing, enhances brand reputation.	Where contractually obliged and funding supported, publication is sought for projects and activities undertaken.	Zero 2021-22.	Annually.

TI & I Year		No. of Projects Completed	No. of publications, posters & conference publications.	Comment
1	2021-22	2	0	
2	2022-23	8	0	As reported in April 2023.
3	2023-24	10	12	As of November 2023.
4	2024-25			
5	2025-26			
Confidence Level.				By: SMF Date: 9.11.23
Data not available		Data Source: Dissemination & Publication Tracker		

KPI 9 IP

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
9	Increase the IP secured through project contracting.	Ensuring IP agreed in contracts.	Securing IP protects the Health Board & university partners.	IP secured where appropriate during project contracting.	IP secured in 2 contracts in 2021/22	Annually

TI & I Year		No. of Projects Signed	Projects where element of IP secured (%)	Comment
1	2021-22		20%	Baseline
2	2022-23		50%	As reported in April 2023
3	2023-24			
4	2024-25			
5	2025-26			
Confidence Level.				
Data not available		Data Source: KPI Source Info.		

KPI 10 Grant applications

No	Objective	KPI Descript or	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
10	Increase the number of successful grant applications	Number of successful grants.	To support R&I work and secure dedicated time.	Minimum of 10 grant applications* per year with an overall success rate of 10%. <i>(*Target reviewed upwards November 2023)</i>	4 successful grant applications in 2021-22	Annually

TI & I Year		Yearly target for no. of grant applications	Grants applied for this year.	Cumulative no. of grant applications	Overall success rate (%)	Comment
1	2021-22	4	4	4	100%	
2	2022-23	4	12	16	56%	
3	2023-24	10*	10	26	46%	As of December 2023
4	2024-25	10				
5	2025-26	10				
Confidence Level.						By: SMF Date: 16/1/24
Data not available		Data Source: Grant Tracker				

KPI 11 Local economic growth

No	Objective	KPI Descriptor	Rationale	Measure	Baseline (21/22 Performance)	Frequency & Mechanism
11	Support Welsh economic growth	The number of Welsh businesses supported	The TI&I wants to support Welsh businesses to grow and develop, helping a cluster of medical technology companies across Wales.	Embark on 1 new project per year	2 collaboration projects with Welsh businesses in 2021-22	Annually

TI & I Year		Cumulative Target for Collaborations with Local Businesses	Collaborations involving Local Businesses	Comment
1	2021-22		2	Baseline
2	2022-23	3	4	As reported in April 2023
3	2023-24	4		
4	2024-25	5		
5	2025-26	6		
Confidence Level.				By: SMF Date: 8/9/23
Data not available		Data Source: KPI Source Info.		