

<b>Name of Sub-Committee:</b>	Research & Innovation Sub-Committee
<b>Chair of Sub-Committee:</b>	Professor Philip Kloer, Medical Director/Deputy Chief Executive
<b>Reporting Period:</b>	August to 11 September 2023

### **Key Decisions and Matters Considered by the Sub-Committee:**

The purpose of this report is to provide the People, Organisational Development and Culture Committee (PODCC) with an update for information on Research & Development (R&D), TriTech & Innovation Group (TIG) and University Partnership activities as well as governance, and the financial position for assurance. The Research & Innovation Sub-Committee (R&ISC) met on 11 September 2023.

The report is also based on meetings and decisions taken at the following:

- Research Quality & Sponsorship Group (4 September 2023)
- Research and Development Leadership Group (16 August 2023)
- TriTech & Innovation Group (24 July 2023)
- University Partnership activities for the reporting period

### **R&I Strategy**

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 second year of the five-year TriTech Business Plan.

Progress against the Strategy and the associated action plan is routinely monitored at the bi-monthly Delivery Leadership Team meetings and reported to R&D Leadership Group and TriTech and Innovation Group. The report provided to the R&ISC described that the R&D and TriTech and Innovation Divisions are on target to deliver the goals contained within the Research and Innovation Strategy 2021-2024. The Year 3 Action Plan for strategy delivery has focused on key areas which need to be prioritised to deliver the strategic goals and planning objectives.

The 2023/24 action plan priorities are as follows:

- Put in place arrangements to grow oncology research trials.
- Adequate funding secured through Health and Care Research Wales to support core research delivery establishment.
- Complete programme of work to establish 'fit for purpose' research facilities at all Hospital sites.
- Increase the number of clinicians with dedicated research time incorporated into their job plans/Performance Appraisal Development Reviews (PADR).
- Achievement of Site Level Research Delivery Plans
- Delivery of year two of the TriTech Business Plan objectives

- Explore and secure opportunities to diversify the TriTech and Innovation portfolio in view of national and international interest.
- Review the size, structure, and capabilities of the TriTech team in view of experience and priorities for the next 12 months.

R&ISC took assurance from the Strategy report detailing progress against the strategic objectives.

## **Governance**

### **Research & Development**

#### **Health and Care Research Wales R&D Framework**

The R&ISC received an update on the new national HCRW R&D Framework, which was published on 21 July 2023. The Framework outlines what 'research excellence looks like' within NHS organisations in Wales where research is embraced, integrated into services, and is a core part of the organisation's culture. A performance review meeting is scheduled with HCRW on 17 October 2023. R&ISC received an internal assessment of our current position against the ten pillars of the framework to inform discussions. R&ISC approved the report and reviewed by the PODCC Chair in September 2023. This final version has been submitted to HCRW for discussion during the review meeting on 17 October and is submitted to PODCC for formal approval.

## **Research Quality and Sponsorship Group**

The R&ISC received an update from the Research Quality and Sponsorship Group (RQSG) and noted and accepted the report with the following points:

- Study Sponsorship: One new application for study sponsorship has been submitted since the previous PODCC meeting.
- Audits: No triggered audits have taken place. No routine monitoring audits have been completed.

The R&ISC received an update on the Biobank and took assurance from the report whilst noting the following:

- Research Biobank: The plan for discontinuing with the Research Biobank is in process and the destruction of samples currently stored for 3 research studies is in progress with advice from the Human Tissue Authority (HTA)/Medicines and Healthcare products Regulatory Agency (MHRA) and Cardiff University Biobank (Material Transfer Agreement being explored). The R&D Division is still on target for ending Human Tissue Authority License for the research biobank by September 2023. The very latest that the Division could end the current license, without incurring additional cost, would be 31 March 2024.

The R&ISC received an update the Medicines and Healthcare products Regulatory Agency (MHRA) and took assurance from the report whilst noting the following:

- An MHRA Inspection Ready draft audit report was submitted to next R&ISC on 11 September 2023; a further report detailing the findings will be presented at the next R&ISC on 11 December 2023.

## **TriTech & Innovation**

### **Operational Report**

The R&ISC received a report on the operations of the TriTech and Innovation Division. The committee took assurance from the report and noted the following:

- Organisational Structure and Staffing: No changes to the organisational structure have been seen over this period.
- Process and Project Tracking Documentation: Tritech 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 and Tritech and Innovation are currently undergoing soft launch over to the new tracker.
- QUALITY MANAGEMENT SYSTEM – ISO 13485 Quality and safety standards for the Tritech 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 from 12 to 15 September 2023 with only 3 minor finding but the QMS passed the inspection.
- Technology Scientific Review Panel (ThoRP) The Technology Scientific Review Panel (ThoRP) has been established; no new projects were reviewed between August 2023 to September 2023. As previously reported to R&ISC, ThoRP is currently undergoing a full review by Tritech and Innovation to ensure it remains fit for purpose. Tritech and Innovation are currently reviewing ThoRP and its potential redesign and will bring suggestions and recommendations to R&ISC when complete.
- Terms of Reference Review: the terms of reference for the TIG group are currently under review particularly around membership to TIG. As these changes relate to governance, when the review is complete the recommendations will be brought to R&ISC for consideration.

## **University Partnerships**

Nothing to note.

## **Discussion items**

### **Research & Development**

#### **Accommodation**

The R&ISC received an update on actions to develop fit for purpose research facilities at two sites.

Bronglais Hospital (BGH): A newly refurbished space in Ty Aeron at BGH was opened on 1 June 2023. External cabling works have yet to be completed, however, the team has relocated and recruitment to portfolio studies has increased.

Withybush Hospital (WGH): Following a site visit and discussions with WGH leads a space (identified as R156 Cardiac Rehab (40m<sup>2</sup>) has been agreed for the WGH Delivery Team to relocate to in July 2023. The timeline for relocation has been delayed due to the Reinforced Autoclaved Aerated Concrete (RAAC) works within the hospital. The RAAC works mean the WGH Delivery Team have been told to vacate their current space and are now working in other parts of

the hospital, or Glangwili Hospital with the existing Delivery Team.

The R&ISC noted the importance of recognising the risk of the RAAC works at WGH to R&D activities and asked for this to be considered in view of the Risk Register. R&ISC noted and accepted the accommodation report.

### **TriTech & Innovation**

The R&ISC received a quarterly activity report detailing updates of note on the following evaluation services provided:

**Nurokor Project:** The current position for Nurokor is still not resolved and final payment has still not been received, the matter is currently with the finance teams with support from the debt collection agency.

**Finalised reports:** Since the last R&ISC two final project reports have been completed and these reports have now been presented to the companies. The projects have been moved to closed:

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

R&ISC took assurance from the activity report.

### **University Partnerships**

The Director of Research, Innovation, and Value reported to the R&ISC 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 in the Autumn. This will support the Health Board's university status and reporting to Welsh Government, which is also due in the Autumn.

R&ISC noted and accepted the university partnerships update.

### **Assurance Items**

#### **Research & Development**

##### **HCRW funding update**

R&ISC members received an update on R&D financial plans and took assurance from the report. The key points included:

- The Delivery Spending Plan for 23/24 has been received. The Research Delivery Total for 2023/24 is £1,196,601. R&ISC were also advised that in the R&D Directors Group, HCRW presented R&D Directors with a proposal to adapt the process for decision-making relating to research delivery funding in 2023/24. The process aims to increase local autonomy in local decision making around the agreed Spending Plan in 2023/24, according to criteria set out by HCRW in their All-Wales Research Delivery Funding guidance (v.3). The end of year forecast

is to break even. This will depend on our Recruitment to Time and Target key performance indicator (set at 70%) which is tracked by HCRW. A 4% national cost pressure is being applied to the HCRW budget for all R&D organisations funded, this will need to be managed internally through scrutiny of like for like replacements and fixed term posts.

- Local Risk – The approach also means cost pressures (if they emerge) will need to be applied across local spending plans (which have previously been managed nationally). This will mean that NHS organisations will need to find other sources of funding to meet those costs (e.g. commercial or other income) or have a plan in place to reduce the costs incurred during the year so that the outturn position of every plan is balanced to zero. As the Health Board manage the local budgets very carefully through monthly meetings, and strict management of costs, then this risk has been assessed as minimal but is recorded through the DATIX system.

## **TriTech & Innovation**

### **TriTech & Innovation Finance Update**

The R&ISC received an update on the financial position of the TriTech and Innovation Division and took assurance from the report. 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. M4 Report 2023/24 – Month 4 position (end of August 2023) is showing a forecast end of year balance as £83,518 underspend. Highlighting costs should be fully accounted for the whole of 2023/24. 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 forecast is on target with the Plan.
- TriTech Key Performance Indicators (KPI(s)) report: All performance indicators, with the exception of two (KPI1 [On-time Delivery of Projects Deliverables] & KPI8 [Increase the number of Publications arising from project activity]), are currently on target. Action plans have been put in place to address the two KPIs not on track. A separate KPI report was taken to PODCC on the 17 August, 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. This was accepted by TriTech and Innovation and a review of the KPI tracker is currently underway with amendments to be presented at the next TIG in September before being submitted to R&ISC (then PODCC) for approval.

## **University Partnerships**

Nothing to report.

## **Information items**

### **Research & Development**

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

**Performance Key Indicators for HCRW being on target (data taken 4.9.23):**

'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.

- RTT – Closed non-commercial portfolio studies (6 month rolling data) = 100%
- RTT – Closed Commercial studies 50%
- Data completeness is 98%

**The 'Out of Hospital/Primary Care' research proposal:** The R&ISC received an update that the Vice Chair has written to the Chair of the All-Wales Vice Chair's group asking for a discussion on how more research can be encouraged in primary care settings. The R&ISC were advised they will be provided with a further update following the discussion.

**Regional Research Collaboration:** Work continues with the wider R&D community and clinical colleagues to resolve some challenges in increasing our commercial and oncology studies. Our Clinical R&D Director is working closely with Swansea Bay's Joint Clinical Research Facility (JCRF) around the oncology and diabetes portfolio.

**Freezer On-Call:** Non-pay costs are currently being reviewed by HCRW, as part of this process R&D have reviewed current arrangements for managing the on-call costs for R&D freezers. These costs will now cease for R&D, and Pathology will manage the on-call system going forward. Consequently, R&D on-call staff are currently progressing through the Organisational Change Process (OCP).

**Communications:** A post funded jointly by Research and Value Divisions (Band 5 Communications Officer) is in progress.

**Pentre Awel:** R&ISC members were advised that the R&D and TriTech and Innovation Divisions continue to explore the potential of relocating from Dura Park to the Pentre Awel scheme. While it offers many opportunities, the decision will ultimately need to be considered in view of the ongoing lease negotiations being led by the Director of Strategy and Planning, due to the financial constraints faced by the Department.

R&ISC took assurance from the Research and Development updates.

**TriTech & Innovation**

Nothing to report.

**University Partnerships**

Nothing to report.

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

PODCC are asked to take assurance from Research & Development (R&D), TriTech & Innovation Group (TIG) and University Partnership activities and decisions reported.

PODCC are asked to note and consider the following matters:

- WH accommodation and the enforced relocation following the RAAC works, and the associated impact to research and development activities.
- The 4% cut in funding from HCRW and the potential impact this may have on fixed-term posts during 2024/24 (funding for these posts is covered up to March 2024)
- The update on the previously advised decision to cease development of the Biobank and to revoke the HTA licence from September 2023 – R&D will advise when this is complete.
- R&I requirements in Pentre Awel; including consideration of collaboration opportunities with education and other functions on the site – subject to agreeable terms.
- Final payment for the Nurokor project remains outstanding. R&D Finance partners continue to work with the debt recovery team to resolve.
- TriTech KPI Tracker is being reviewed and re-framed to ensure clarity around each KPI. This will be presented to R&ISC in December 2023 and PODCC in February 2024.
- PODCC are asked to approve the publication of the Health and Care Research Wales Research and Development (R&D) Framework and approve the content of the self-assessment framework, in advance of the Welsh Government.

## Risks / Matters of Concern:

### R&D risk:

Total Number of Risks	3
New risks	0
Closed/Archived risks	2
No change in risk score →	2
Increase in risk score ↑	1
Reduction in risk score ↓	0

Risk Reference and Title	Date Risk Identified	Executive Director	Current Risk Score	
1036 – Inadequate clinical space in Withybush Hospital	26.05.2016	Professor Philip Kloer	16	Score was 12 prior to R&ISC, where members agreed the 'likelihood' score should increase to 4, thus making the risk score 16.
1492 – annual spending plan as agreed with	29.09.2022	Professor Philip Kloer	9	Capacity funding has been identified to cover some fixed

HCRW fluctuates and is monitored and reviewed monthly				term contracts for the first 6 months of 2023/24.	
1160 – Lack of research leadership (Directorate Level)	07/08/2018	Professor Philip Kloer	9	In May 2023, the likelihood score was reduced in view of increased numbers of staff with research leader time awards.	

R&ISC received the R&D risk update on 11 September, 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	1
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
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	31/08/2022	Professor Philip Kloer	2x3=6 →	It is difficult to prevent emerging competitors, but the impact of

competitors developing a similar model to TriTech			(reviewed 23/08/23)	competitors can be reduced by maintaining a competitive advantage. There is potential for other Health Boards to adopt the TriTech model.  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.
1508 – The risk of a lack of clinical leadership to support TriTech projects	31/08/2022	Professor Philip Kloer	<b>3x2=6</b> → (reviewed 23/08/23)	No issues have arisen thus far in identifying clinical leads to take on research or evaluation projects.  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.  This risk remains open as there is the potential for an increase in risk score in the future.
1507 – TriTech and Innovation: Financial Delivery Year 3	01/04/2022	Professor Philip Kloer	<b>4x1=4</b> → (reviewed 23/08/23)	Current demand for services is sufficient to meet income generation targets with 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.

Since the previous PODCC report, a full review TriTech & Innovation risk register has been undertaken. One risk has been closed (1506 – Workforce Retention- as there is currently no staff retention risk. The team currently has sufficient capacity) and the current risk score remains unchanged for all the other risks. All risks are at Service Level with a current score of 6 or lower. R&ISC reviewed the TriTech risk report on 11 September and noted and accepted the report, based on the agreement that risk 1507 be formally reviewed and considerations given to

mitigating the risk and raising the score if required. This review will be presented to the next R&ISC meeting for discussion.

### **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 & Futures
- TriTech & Innovation Activity Report
- TriTech Revised KPI Tracker
- TriTech Risk Register
- TriTech Financial Report
- National Developments
- Any Other Innovation Papers
- Reports on Strategy Progress
- Strategy Action Plan for 23/24 & progress report
- University Partnerships
- Update from Partnership Meetings

#### **Date of Next Meeting:**

11 December 2023