Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales Commercial Research Delivery Centre Funding Requests VPAG (Stream 1) investment for clinical trials

Guidance

1. Overview

Health and Care Research Wales are opening a call for members of the Wales Commercial Research Delivery Centre (CRDC) to submit requests for funding required to support the delivery of commercial pharmaceutical interventional research, where the cost will be incurred from the 1st April 2025.

The purpose of the funding is to increase commercial research delivery capacity by expanding on and enhancing existing dedicated commercial clinical research facilities that are part of the Wales Commercial Research Delivery Centre (Wales CRDC). This must accelerate the delivery of commercial pharmaceutical interventional research for the measurable benefit of health and wealth in Wales. VPAG funding is fixed term for 5 years in total and therefore it is expected that applicants make a strong case to demonstrate that the investment secured will be sustainable through income generation in a defined timescale.

The aim is to:

- Make Wales a key partner in the UK offer for commercial research delivery through the UKCRDC as well as a competitive partner delivering the highest quality research and harnessing expertise and strengths.
- Provide additional capacity to conduct commercial pharmaceutical interventional research within existing clinical research facilities in Wales.
- Have commercially active sites adopting standardised costing and contracting and delivering standard set-up times and performance which meets the expectations of industry sponsors
- Develop and support decentralisation of clinical trials to primary, community and social care settings to make taking part in research as easy as possible for participants
- Optimise referral pathways including NHS to NHS and NHS to non-secondary, community and other settings
- Support agility and responsiveness in research delivery related to the clinical trial pipeline in Wales
- Increase research inclusion to ensure people from all eligible communities and those living with the greatest burden of disease can participate in clinical trials.
- Work collaboratively with all parts of the Health and Care Research Wales research infrastructure and aligned organisations within the devolved nations.
- Work to provide training to enhance skills and workforce development to build further capacity and expertise for the delivery of commercial pharmaceutical interventional research

2. Eligibility Criteria

One application will be accepted on behalf of each existing clinical research facility which are part of Wales CRDC (please see Appendix one). Applications will need to clearly demonstrate the following:

- Clear vision which demonstrates impact of funding received, value for money and a sustainability plan
- Strict adherence to national mandates and initiatives aimed at streamlining and expediting the delivery of commercial research, including but not limited to comprehensive compliance with the National Contract Value Review process
- Implementation of sound financial practices which are transparently reported. These include full cost recovery, effective fund management across financial years to optimise the utilisation of capacity build and ensuring capacity build funding is spent as intended. This reporting will be considered on an all-Wales level with the ambition to ensure commercial research delivery capacity growth
- Commitment to increase the delivery of commercial pharmaceutical interventional research and meet the UK metrics requirements
- Commitment to work with one Wales models and approaches, where possible and whenever possible
- Maximise Wales potential in relation to geography, patient demographics and disease prevalence factor into the feasibility of clinical trials and the selection of appropriate research locations

3. Out of Scope

Below are examples of out-of-scope requests (the list is not exhaustive):

- Requests related to the direct delivery of non-commercial research
- Student posts (such as Master's Degree and PhD)

Requests that relate to infrastructure outside of the designated CRDC infrastructure will be invited via a separate Stream 2 funding application process

4. How to apply

Please complete:

- The form below by answering the questions in each section
- The spending plan attached (see section 7 for more details)

To support you with your funding requests, a BI dashboard and information pack on commercial site ID data has been produced.

Commerical Site ID Data.pdf

Submission Deadline
The closing date for submission of the funding requests is **31/01/2025 at 23:59**. Funding requests should be submitted to research-fundingsupport@wales.nhs.uk.

Applications will not be accepted after the deadline above.

Questions or Queries

If you have any questions or queries regarding this funding call, please contact research-fundingsupport@wales.nhs.uk

5. Review & Decision Process

Review and approval of funding applications will take place in early February 2025 and outcomes communicated to applicants by end February 2025 at the latest.

6. Funding Requests Form

Applicants are asked to use plain English and avoid jargon where possible. Abbreviations should be spelled out and technical terminologies explained in the first instance. Word count has been indicated and is a maximum and not a requirement. Please answer as concisely as possible.

Questions 1 to 4 of the funding request form provide the narrative description of your strategic research delivery plans for this investment to complement the detailed request in the financial plan (see section 7) which includes item-specific justification.

CRDC CRF Host organisation:	
CRDC CRF Lead Contact*	
Individual submitting application if different from CRDC CRF Lead Contact:	

*The CRDC Lead contact is the named individual able to provide further information/discussion about the application

Question one: Please provide an overview of the clinical research facilities that are provided and how this will be enhanced to contribute to the Wales CRDC? Maximum 1,000 words
• Explain what existing clinical research facilities you have in place, USP, track record, reputation • Explain how the funding will allow you to expand and enhance the existing clinical research capability and capacity and how this will contribute to the Wales CRDC; support one Wales approaches or models, where relevant; provide patient access to commercial pharmaceutical interventional trials across Wales • Explain how the funding will provide value for money

Question two: How will the funding request increase commercial pharmaceutical interventional research activity? Maximum: 1,500 words

- Explain how the funding will increase commercial pharmaceutical interventional research activity by considering current activity vs projected activity
- Explain whether the funding is to enhance area(s) of strength and/or opportunity for growth in the pipeline of commercial pharmaceutical interventional studies
- Explain, where relevant, how the funding will provide opportunities for integration of NHS and non-NHS organisations to best facilitate research referral patient recruitment and participation across Wales
- Explain, where appropriate, how the funding will develop research delivery capacity and capability in the research delivery workforce by developing appropriate skills and training
- Explain how the funding will enhance commercial sponsor engagement and build Wales's reputation in commercial research delivery

Question Three: What impact will the funding request have on the set-up and delivery of commercial pharmaceutical interventional research activity? Maximum 500 words

Please identify specific (SMART) objectives that will be used to track the impact of the investment. Please include details of how impact will be monitored to demonstrate success.

Note, you may want to refer to the BI dashboard provided and consider the following in relation to the above:

- Number of industry trials initiated per year
- Number of participants recruited to industry trials per year
- Proportion of industry trials initiating within a set time (e.g *Proportion of pharmaceutical industry interventional clinical trials opening recruitment at all sites within 60 days of receiving regulatory approval)*
- Geographical spread of industry trials across the UK

Question four: Optional supporting evidence Maximum: 750 words
There is the opportunity to provide up to three case studies highlighting previous successes in delivering commercial pharmaceutical interventional research and/or how additional funding/pump priming has resulted in success

7. Financial Plan

Prior to completing the financial plan template, it is important applicants have a good understanding of the following:

- The financial plan should provide an accurate breakdown of the costs that will be incurred.
- You must provide a clear justification for resources, referencing the narrative strategic plan above where appropriate.
- Further itemisation of costs and methods of calculation may be requested to support the application at a later date.
- Applications should be costed at current prices, based on current salary scales and scale increments. Annual salary increments or other equivalent annual increases should be included in future years but not any other anticipated pay increases (e.g. nationally agreed pay awards). Do not include estimated uplift(s) for inflation. Should an award be made, annual uplifts may be provided, depending upon the budget available.
- We would expect standard NHS accounting policy and guidance to be followed in determining the appropriate costs
- Years should be calculated starting from the anticipated start date of the proposed requests
- Health and Care Research Wales reserves the right to audit organisations in receipt of funding to confirm the actual use of funds

A financial plan template has been created for all funding requests. Please add each funding request to a separate row within the spending plan template, profiled across the relevant financial years, completing each column. The following information is requested:

- **Column A:** Post Title / Non-Staff Cost
- **Column B:** Department
- **Column C:** Department Additional detail
- **Column D:** Detailed description and justification
- **Column E:** Managing Specialty (Select from Dropdown menu)
- **Column F:** Managing Specialty Comments (Free text field to provide further information regarding Specialty Areas)
- **Column G:** Impact (Free text field, to indicate the expected level of impact of the investment*, IE Immediate/Foundation/Developmental/Unblocking*)
- **Column H:** Impact Term *(Dropdown menu: Short/Medium/Long-term)*
- **Column I:** Band (if applicable, pay costs only)
- **Column J:** WTE (if applicable, pay costs only)
- **Column K:** Forecast Gross Expenditure 2025/26
- **Column L:** Forecast Cost Recovery 2025/26 (amount of commercial income generated, forecasted to be recovered against the initial investment)
- **Column M:** Forecast Net Expenditure 2025/26 (Automatically calculated based on figures populated in columns K & L)
- **Column N:** Forecast Gross Expenditure 2026/27
- **Column O:** Forecast Cost Recovery 2026/27 (amount of commercial income generated, forecasted to be recovered against the initial investment)
- **Column P:** Forecast Net Expenditure 2026/27 (Automatically calculated based on figures populated in columns N & O)
- **Column Q:** Forecast Gross Expenditure 2027/28
- **Column R:** Forecast Cost Recovery 2027/28 (amount of commercial income generated, forecasted to be recovered against the initial investment)
- **Column S:** Forecast Net Expenditure 2027/28 (Automatically calculated based on figures populated in columns Q & R)
- **Column T:** Forecast Gross Expenditure 2028/29
- **Column U:** Forecast Cost Recovery 2028/29 (amount of commercial income generated, forecasted to be recovered against the initial investment)
- **Column V:** Forecast Net Expenditure 2028/29 (Automatically calculated based on figures populated in columns T & U)
- **Column W:** Additional Comments to further support the request (Optional)

8. Declaration - Adherence to national mandates and funding requirements

Applicants are required to adhere to:

1. National mandates and initiatives aimed at streamlining and expediting the delivery of commercial pharmaceutical interventional research, including comprehensive compliance with the National Contract Value Review process
2. The use of Model Clinical Trials Agreement (mCTA), Clinical Research Organisation Model Clinical Trials Agreement (CRO-mCTA)
3. Apply one Wales approaches and models, where applicable
4. Develop and implement a financial sustainability plan
5. Adhere to all Wales R&D finance policy
6. Provide full financial commercial income transparency on a quarterly basis
7. Adhere to the terms and conditions outlined in the funding award letter

Submission of this application confirms you accept these conditions.

Appendix One