
Vaccine Innovation Fund

Application Guidance

Introduction

The COVID-19 pandemic provided an opportunity for the UK to showcase its capabilities in vaccine research and development, further solidifying its position as a global leader in this critical area of public health.

The UK Vaccine Innovation Pathway (VIP) programme represents a strategic initiative to capitalise on the momentum and expertise gained during the COVID-19 pandemic in vaccine research and development. By leveraging the innovative approaches and research assets established during the pandemic, the programme aims to expedite the clinical trial process for vaccines and cement the UK's position as a global leader in this vital area of public health.

The VIP is a cross-sector programme supporting [The Future of UK Clinical Research Delivery](#) – a collective vision which aims to achieve faster, more efficient and more innovative clinical research delivery – making the UK one of the best places in the world to conduct research.

As part of a wide strategic partnership with the UK Government, Moderna and the UK Vaccine Innovation Pathway have established the Vaccine Innovation Fund, a multimillion-pound fund to invest in sustaining and enhancing the UK's capabilities in vaccine research beyond the immediate crisis of the pandemic. The Vaccine Innovation Fund will be allocated through a series of funding calls conducted by the UK Vaccine Innovation Pathway on an annual basis.

The 2024 Vaccine Innovation Fund competition seeks applications focusing on:

- Challenge category 1: Developing capacity and capability in clinical trials pharmacy with a focus on developing and testing novel models for delivering clinical trials of advanced therapy medicinal products (ATMPs).
- Challenge category 2: Widening participation in clinical trials of vaccines with a focus on developing and testing novel models for delivering clinical trials of vaccines in GP practices and/or residential care homes.

Applications for the Vaccine Innovation Fund Competition 2024 will be open from 11th March 2024 and close at 12 noon on 17th April 2024. Applications must be made via the Vaccine Innovation Fund Research Management System (RMS). Please login to the RMS at <https://pmo.ccgranttracker.com>. Instructions for registering to use the RMS can be found in Annex 2 - Registering to Use the Research Management System to Submit an Application of this document.

The competition is a standalone competition aimed at supporting innovative projects and partnerships which will accelerate the set up and delivery of clinical trials of vaccines and cancer therapeutics. The early-stage innovation contracts are for a maximum of 24 months (from no later than October 2024) and from £200,000-£500,000 per project.

Aim of the scheme

The scheme provides funding to organisations in England, Wales, Scotland and Northern Ireland to meet the eligible costs of trialling innovative ways of working in setting up and delivering clinical trials of vaccines and cancer therapeutics.

Selection criteria

An Independent Selection Panel will be established to make recommendations to the Moderna projects. The committee will review applications and make recommendations based on the following selection criteria:

- The **quality and breadth of the proposed innovation project including impact measures and the potential of the project to be sustained and scaled up across the UK.**
- The **strength of the plan** for the proposed innovation project **including** the leadership and governance arrangements, plans to support skills and workforce development for clinical trials of vaccines and cancer therapeutics, and a clear commitment to equality, diversity and inclusion.
- The **strength of partnerships and collaborations** including with HEIs, charities and NIHR-funded research infrastructure (LCRNS/RRDNS; CRFs, ECMCs) and equivalent research delivery networks in the devolved administrations.
- **Value for money.**

The overarching NIHR principles of transparency and competition relating to NIHR funding calls will be applied.

Eligibility criteria

All NHS organisations, GP practices and residential care homes in England, Wales, Scotland and Northern Ireland are eligible to apply.

Vaccine Innovation Funding will be awarded to a **single** lead organisation. The designated organisation may collaborate with other NHS organisations, HEIs, GP practices, community hospitals or residential care homes and may pass funding to them via an appropriate mechanism, such as a subcontract. Reasons for involving other organisations in the proposed project will need to be justified in the application including how the proposed partnership(s) will address the challenges identified by the Vaccine Innovation Pathway programme for 2024. Please list co-applicants and outline the project team in the project proposal section of the application form.

Scope of the award

As part of a wide strategic partnership with the UK Government, Moderna has established the Vaccine Innovation Fund, a multimillion-pound fund to invest in sustaining and enhancing the UK's capabilities in vaccine research beyond the immediate crisis of the pandemic.

The 2024 Vaccine Innovation Funding call has two challenges:

1. **To develop capacity and capability in clinical trials pharmacy with a focus on developing and testing novel models for delivering clinical trials of advanced therapy medicinal products (ATMPs).** mRNA technology allows the production of diverse vaccines and treatments in a shorter time frame and with reduced expense compared to conventional approaches. As a result, there has been a surge in the use of mRNA-based therapeutics in recent years with the aim of encoding tumour antigens for cancer vaccines, cytokines for immunotherapy, tumour suppressors to inhibit tumour development, chimeric antigen receptors for engineered T cell therapy or genome-editing proteins for gene therapy. Many of these therapeutics have shown promising efficacy in preclinical studies, and some have even entered clinical trials. mRNA cancer trials have been classed by the regulators as Advanced Therapy Medicinal Product (ATMP) clinical trials. In 2023 the UK health research system engaged in the set up and delivery of the first cohort of early phase trials of cancer therapeutics. Our cancer vaccines forum identified clinical trials pharmacy and ATMP readiness as a critical factor in the success of both set up and effective delivery of these complex cancer trials. This was also the feedback we received from our cancer strategy workshop. We encourage applicants to consider the following as potential parts of their application:

- Development of partnership models to scale up aseptic capacity.
- Innovative approaches to pharmacy workforce challenges.
- Cold chain optimisation for mRNA investigational medicinal products.
- ATMP readiness, including equipment and training.

The list above is not intended to be exhaustive, and we would welcome ambitious proposals that target the clinical trials pharmacy challenge.

2. To widen patient participation in clinical trials of vaccines for infectious diseases.

Clinical trials of vaccines for infectious diseases form an integral part of the UK public health strategy and need to deliver recruitment at scale and speed that is at the same time representative of the diversity of the UK population.

The experience with COVID-19 vaccine trials highlighted the necessity for a comprehensive and coordinated approach throughout the healthcare system.

To effectively conduct clinical trials, especially those related to vaccines, it's crucial to have a system-wide coordinated strategy. This strategy should encompass various healthcare settings beyond acute care hospitals, including general practitioner (GP) practices, residential care homes, mobile research units, and community centres. By expanding the locations where trials can be conducted, researchers can reach a broader and more diverse population, which is essential for ensuring that trial results are applicable to different demographic groups.

Moreover, involving diverse settings in clinical trials not only increases representation but also enhances accessibility for potential participants. This can lead to faster recruitment and more efficient trial processes. Additionally, involving community-based locations can help build trust and engagement among participants, which is vital for the success of clinical trials.

In essence, a system-wide coordinated approach to clinical trials, with the capacity to conduct trials in various healthcare settings, is essential for responding effectively to public health needs and ensuring the success of vaccine development efforts, particularly in the context of infectious diseases like COVID-19, flu, RSV and Mpox.

We encourage applicants to consider proposals for the development of innovative partnerships including GP practices and/or care homes and other non-hospital settings which will accelerate the set up and delivery of clinical

trials of vaccines for infectious diseases. For the development of these novel models for clinical trials delivery applications can include:

- Development of research capability including research governance and staff training.
- The cost of small equipment (for details please see Annex 1).
- Costs for hiring mobile research units or community space.
- Community based projects aimed at building trust and engagement among participants.

The list above is not intended to be exhaustive, and we would welcome ambitious proposals which will aim to improve access to clinical trials of vaccines for infectious diseases.

Funding

A total of up to **£2 million** is available for this round of the Vaccine Innovation Fund. Individual applications must be for total eligible costs of between £200,000 and £500,000. Information on eligible costs is provided at Annex 1.

- Funding will be awarded for up to a **two-year** period (starting no later than 1 October 2024).
- The amount of funding allocated to each project will be determined by the scale, nature and quality of the proposed innovation project.
- The number of projects to be funded has not been pre-determined. The number of awards will reflect the quality of the applications and the funding available for this round.

Note: No capital funding (for tangible fixed assets such as buildings and equipment costing over £10,000) will be available through this funding competition. Applications should only include innovation projects that can be undertaken with the existing or planned facilities which already have confirmed funding.

The competition process and timetable

Date	Milestone
27 th February 2024	Webinar briefing for potential applicants
1 st March 2024	Publication of Frequently Asked Questions and a recording of the webinar
11 th March 2024	RMS application form opens

17 th April 2024	Closing date for receipt of applications by 12 noon
June 2024	The Independent Selection Panel reviews applications and makes recommendations on allocation of funding
July 2024	UK VIP PMO confirms successful projects
No later than October 2024	Funding for selected projects commences

Contracting Process Overview

- Moderna is the source funder for the Vaccine Innovation Fund, having agreed to support UK efforts to transform its Vaccine Innovation Pathway to delivery against the opportunities described by the Lord O'Shaughnessy review.
- After discussions with NIHR, it was decided that Moderna would contract directly with VIF awardees selected by NIHR's review panel, with a key consideration being the enhanced payment and delivery flexibility this model allows.
- To ease the administrative burden on Awardees, Moderna is working with NIHR to base the contracting template for the VIF on existing NIHR model contracts, the terms of which are accepted by the sector. There will not be an opportunity to negotiate on the contractual terms, although Moderna reserves the right to show discretion based on a case-by-case approach.
- The contracting process will be complete by September 2024.
- All VIF Awards are made subject to contract.

Questions

If you have any questions about the process or scope of the call, please contact vip@nihr.ac.uk. Answers to questions will be published on the FAQs document which can be found on the homepage of the Vaccine Innovation Fund site.

ANNEX 1: Application Finances and Eligible Costs

The purpose of the funding is to deliver the project that is in your application. General overhead costs and other non-project related costs are not in scope.

Funding awards will be made to the designated Lead Organisation that employs the Lead Applicant but it is permissible for funds to flow to other NHS organisations, HEIs, GP practices, community hospitals or residential care homes via a suitable mechanism such as a subcontract

Specific points for applicants to note:

- The Vaccine Innovation Fund awards will range between £200,000 and £500,000. Applications outside of these limits will not be considered.

Please note that the finance form is asking for indicative costings between 1st August 2024 and 31st July 2026. Depending on when projects propose to start- no later than 1st October 2024- and contracting timelines Moderna will finalise the payment schedules.

- After review and a project is selected as being shortlisted for funding, Moderna will reserve the right to conduct due diligence of the proposed costs with the aim of funding 100% of project related costs that have sufficient justification.

- Funds will go through the Contracting Lead Organisation. Only one lead organisation ('Contracting Organisation') will sign a contract with Moderna and receive and administer funds. The designated Contracting Organisation will be expected to manage onward disbursement to partners. Payments will be made in arrears quarterly or annually. The Contracting Organisation is the organisation where the Contracting Lead Applicant is employed.

- Organisations should use costing models that are specific to their business model and be able to provide a justification for costing models if a project is identified as being potentially fundable. Further itemisation of costs and methods of calculation may be requested to support the application at a later date

- Within the financial envelope, the panel will consider the cost of small equipment of up to £10,000 for each piece of equipment with appropriate justification. Items of equipment valued at £250 or more must be itemised separately; however, grouping the same type of equipment is permitted. Costs of computers are normally restricted to a maximum of £1,000 each excluding VAT. A statement of justification must be included

in the relevant 'Justification' line of the "Other Costs" tab of the Finance Form for any purchase above this limit.

- Equipment must exclude VAT, but if the organisation incurring the cost is not VAT registered and cannot claim back VAT on cost items, then it would have to enter the gross value of a cost item (including VAT) on the financial plan. You will need to seek advice from the organisation that the piece of equipment is purchased from regarding its VAT status.
- Leasing costs are ineligible costs under this call except for hiring mobile research units or community space.
- Equipment warranties that incur an additional cost are ineligible costs under this call.
- Equipment purchased with funding from this call should be credited to Capital Departmental Expenditure Limit (CDEL), and the subsequent expenditure on the equipment debited to CDEL once the equipment has been purchased. The funding provided is not outside of NHS system capital allocations, but the net impact of these transactions should be nil as the debit and credit cancel each other out. It is important that the VIF and subsequent equipment spend by the NHS Trust both need to be recognised in the same financial year. However, if the spend is more than the grant then there would be a net impact on NHS Trust's system allocation.
- General refurbishment, even of research areas, is not eligible for this call. However, where a capital investment of equipment has been made, refurbishment of an appropriate space to use the equipment can be included within the application, if required.
- Journey costs - Enter the total cost of transport for all journeys for destination/purpose. If travel is by car, apply your institution's mileage rates (however this should not exceed HMRC approved mileage allowance payments, which is 45p per mile for the first 10,000 miles and 25p thereafter). Travel by the most economic means possible is encouraged; NIHR funding schemes do not usually fund first class travel.
- Subsistence covers accommodation (if necessary) and meals associated with the travel, excluding any alcoholic beverages.
- Attendance at UK or international conferences needs to have a direct link to the project and be justified. General conference attendance will not be funded.
- If applicants believe that NHS support or treatment costs are required as part of the project, detailed justification will be required.

Completing the Finance Form

There is a separate Vaccine Innovation Fund 2024 Call Finance Form that needs to be completed and submitted on the Vaccine Innovation Fund Research Management System. The Lead Organisation must submit one Finance Form for the application that includes information from other organisations that may act as subcontractors. Applicants should enter information into boxes marked in yellow on the Finance Form and not adjust boxes in grey that are designed to perform calculations. The financial plan should provide a breakdown of all the requested staff direct costs, other direct costs, reasonable NHS indirect costs and eligible NHS Support Costs and for which funding is being requested. Please note that all costs may be reviewed in detail for projects identified as being suitable for funding before a contract is issued by Moderna so applicants should ensure that they have used a robust method to estimate costs that can be shared with Moderna. The final decision whether to enter into a contract with the Lead Organisation and the sum of funding provided rests with Moderna.

Information need to be entered on to the following tabs on the Vaccine Innovation Fund 2024 Call Finance Form:

- **Summary Tab** - The Lead Applicant needs to complete the four boxes highlighted in yellow: Title of Application; Lead Applicant; Lead Organisation, and; Finance and Contract Manager for Lead Organisation. Other boxes on this tab should not be changed.
- **Staffing Costs Tab** - Information should be provided for staffing costs for the lead organisation and separate costs for Collaborating Organisations that will be managed under subcontract by the Lead Organisation. Please complete all columns (Name of member of staff (if known), Role in Project, Job Title, Organisation, Basic Salary (£) and additional (ON) Costs (£). Please add additional rows if required
- **Other Costs Tab** - Information should be provided for the Lead Organisation and Collaborating Organisations about non-staffing costs requested. The form has the following options for the category of costs: Travel costs; Equipment costs; Consumables costs, Patient and Public Involvement, Engagement and Participation (PPIEP) costs; Dissemination costs, Costs of training delivery staff; Hire of venues; Hire of mobile units; Other Direct Costs and Indirect Costs; Estimated NHS support & treatment costs. Please choose the most appropriate category for each cost with “Other Direct Costs and Indirect Costs” used for any cost not covered by other categories. A short justification for non-staff “Other Costs” should be entered on each line summarising the purpose of the requested funding and how costs were estimated. Please add additional rows if required.

For all items requested, costs must be broken down into three financial periods:

- 1st August 2024 to 31st December 2024

- 1st January 2025 - 31st December 2025
- 1st January 2026 - 31st July 2026

Costs entered for each financial period should be the forecast actual spend in the period rather than a pro rata value of the total cost over the project timeline. If project activities do not start on 1st August 2024 or will complete before 31st July 2026, please ensure that the entered costs reflect the dates in which costs will be incurred. This breakdown into the specified financial periods is required for Moderna to allocate budget for approved projects in the Moderna financial calendar. The spreadsheet will automatically calculate total funding requested for each line item and financial period.

Please note that the finance form is asking for indicative costings between 1st August 2024 and 31st July 2026. Depending on when projects propose to start- no later than 1st October 2024- and contracting timelines Moderna will finalise the payment schedules.

If organisations are building in an inflationary increase or pay salary scale progression into costings this should be noted in the application.

In all cases, the value for money of the proposal will be an important selection criterion so please provide a justification for requested costs.

A fully completed Vaccine Innovation Fund 2024 Call Finance Form must be uploaded to the Vaccine Innovation Fund Research Management System as part of the application. Failure to submit a Finance Form, or submitting a Finance Form without the requested information may result in your application being excluded from the review process.

Annex 2 - Registering to Use the Research Management System to Submit an Application

Registration instructions:

1. Go to <https://pmo.ccgranttracker.com>.
2. As a new user, on the right-hand side of the homepage, select 'Register'.
3. Enter your institutional email address and select 'Verify'.
4. An email will be sent to the provided email address for you to authenticate your account. This email contains a hyperlink that, when clicked, will redirect you automatically back to the registration form.

5. Enter your details. Questions accompanied with the red dot are mandatory and must be completed.
6. Ensure the consent question is answered, entitled 'Communication Preferences' (situated at the bottom of the page).
7. Select the 'Terms and Conditions' and, once read, tick the confirmation box. Click 'Next'.
8. Your account will now be sent for review by a member of our team. Please note that verification can take up to 2 working days.
9. Upon successful verification, an email containing a link to create your password to subsequently gain access to the system will be sent to the provided email address.
10. Please add pmo@ccgranttracker.com to your trusted senders as these emails are prone to going to Spam or Junk folders.

Please [click here](#) for additional guidance on the RMS portal.

Change log

Date	Change	New version
11 Mar 24	Original	V1.0
12 Mar 24	Revision of finance guidance in Annex 1 to clarify hiring mobile research units and community space costs eligibility	V1.1
20 Mar 24	Addition to Eligibility Criteria to highlight where co-applicant details can be added to the application	V1.2