Department of Health & Social Care

UK Vaccine Network Project Annual Review - 2019/20

Global Health Security Programme

November 2020

Clearance Checklist

	Name	Date
Quality Assurance sign off	Ned Carty, Portfolio Manager, Major Programmes, Capital Delivery and Investment, Finance Directorate DHSC	03/09/20
External Assurance - Independent body sign off	Jo Mulligan, Senior Health Advisor, Research and Evidence Division, DFID	26/08/20
Project Board sign off		06/11/2020
Global Health Security (GHS) Programme Board sign off		16/09/20

Abbreviations

BBSRC	Biotechnology and Biological Sciences Research Council
CEPI	Coalition for Epidemic Preparedness
DCVMN	Developing Countries Vaccine Manufacturers Network
DHSC	Department for Health and Social Care
EPSRC	Engineering and Physical Sciences Research Council
GAMRIF	Global Antimicrobial Resistance Innovation Fund
GHS	Global Health Security
LMIC	Low and Middle Income Countries
NETSCC	NIHR Evaluation, Trials and Studies Coordinating Centre
NIHR	National Institute for Health Research
ODA	Official Development Assistance
SME	Small- to medium-sized enterprise
ToC	Theory of Change
UKRI	UK Research and Innovation
UKVN	UK Vaccine Network
VfM	Value for Money

Introduction

Outline of Global Health Security programme

In the 2015 spending review, the Global Health Security (GHS) programme was given £477m of UK Official Development Assistance (ODA) funding to develop projects for the benefit of low and middle income countries (LMICs), with the aim of contributing to a 'world safe and secure from infectious disease threats and promotion of Global Health as an international security priority.' This accounts for 34% of total Department of Health and Social Care (DHSC) ODA funding. The programme is made up of five projects: Fleming Fund, Global Antimicrobial Resistance Innovation Fund (GAMRIF), UK Public Health Rapid Support Team, International Health Regulations Strengthening project and the UK Vaccine Network project. Through delivery of each of these projects the programme aims to support ODA eligible countries to:

- prevent and reduce the likelihood of public emergencies such as disease outbreaks and antimicrobial resistance;
- detect health threats early to save lives; and
- provide rapid and effective response to health threats.

Outline of project

The UK Vaccine Network project is a £110m ODA-funded project that supports the development of vaccines and vaccine technologies for 12 priority diseases of epidemic potential in LMICs. Furthering the development of these vaccines and associated technologies will ultimately enable disease outbreaks to be prevented through proactive vaccination campaigns, or controlled upon detection through rapid development of new vaccines and/or responsive vaccination campaigns.

An investment strategy for the project was developed using advice from the UK Vaccine Network (UKVN), a group of experts from academia, industry, government and philanthropic organisations and chaired by the DHSC Chief Medical Officer. To implement this investment strategy, a series of open research calls were run, and 78 projects selected for UKVN investment. Research projects in the UKVN research portfolio focus on:

- late-stage preclinical development and early-stage clinical development of vaccine candidates for the priority pathogens

- development of novel vaccine platforms and manufacturing techniques to enable vaccines against unknown pathogens to be developed faster and improve accessibility and delivery of vaccines in LMICs

- associated technologies and epidemiological work that would support effective vaccine deployment in an outbreak

A range of cross-government partners with the required experience and expertise delivered the research calls and manage the resulting research projects. UKVN project delivery partners are:

- UK Research and Innovation (UKRI) organisations: the Biotechnology and Biological Sciences Research Council (BBSRC), the Engineering and Physical Sciences Research Council (EPSRC) and Innovate UK

- two commissioning facilities of the National institute for Health Research (NIHR): the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) and the Central Commissioning Facility

Alongside the delivery of the UK Vaccine Network research portfolio, the project team are responsible for the continuation of the UKVN expert group, which now holds annual meetings to understand and advise on wider policy issues facing vaccine development and manufacturing.

Outline summary of project's last year annual review

1. Project management: Amber/Green
2. Finance: Amber/Green
3. Theory of Change: Not applicable
4. External engagement: Amber

Overall delivery/ confidence RAG rating from last annual review: **Amber/Green**

Summarised key recommendations from the previous review

The following recommendations were made and accepted by the programme board at the last annual review:

Project Management

Recommendations	Current status
1. The biggest ongoing risk to project delivery is the accuracy of financial forecasting. Recommendations to improve this are covered in the finance section.	**COMPLETE**
2. The use of scorecards to assist performance management and relationships with delivery partners was instigated this year. Recommendation: this process should be reviewed by the end of quarter 2 to understand value and identify potential improvements.	**COMPLETE**
3. Develop clearer mechanisms for output/impact reporting from projects to DHSC, through alignment with delivery partner existing mechanisms, where possible.	**IN PROGRESS**
4. Review and update the logframe, including reviewing targets set in subsequent years considering this year's findings and update the indicator for follow on funding to clarify what is being measured.	**COMPLETE**

Finance

Recommendations	Current status
5. This year has highlighted the importance of understanding the underlying financial processes of delivery partners to ensure accurate forecasts. This enhanced understanding of the limitations of both DHSC and partner financial systems has resulted in a need to ensure accurate risk adjustment is carried out by DHSC as well as continuing ongoing actions to improve forecast accuracy with partners.	**IN PROGRESS**

Theory of Change

See annex for UKVN Theory of Change

Recommendations	Current status
6. Relevant to assumption 7 (other funders providing follow-on funding), the vaccines team should increase coordination with the Coalition for Epidemic Preparedness (CEPI) and other downstream vaccine R&D funders to proactively support the transition of projects between funders, in the context of open competition, and to ensure future funding strategies are aligned.	**COMPLETE**
7. Assumption 8 (phase-2 ready vaccines are effective when deployed) should be updated to reflect the need for multiple phase-2 ready candidates before this assumption is reasonable.	**COMPLETE**

8. An additional assumption should be added relating to the selection, regulation and availability of the most successful and suitable vaccine candidates following phase 2 trials. The UK Vaccine Network project team should work with relevant stakeholders, including LMIC stakeholders, to assess these routes to impact for the vaccine candidates in the portfolio and identify if/how corresponding bottlenecks and challenges can be addressed globally.	**COMPLETE**
9. For any future iteration of the UKVN and associated funding, the project team should: o consider and incorporate learning from the large-scale use of the experimental Ebola vaccine in a complex outbreak environment. Learnings from this experience, will inform assumptions 9-11, providing evidence that should be utilised in future programme design. o look to increase links to LMICs that are affected by the relevant diseases, engagement should be both at the project design stage and within R&D collaborations from the outset of projects.	**IN PROGRESS**

External Engagement

Recommendations	**Current status**
10. Focus 2019/20 communications strategy on delivering communications which provide a narrative of the whole UK Vaccines Network project portfolio, to complement ongoing work highlighting individual projects.	**UNDER REVIEW**

11. Maintain momentum of external communications by considering timing of communications activities in the 2019/20 communications strategy and balancing the types of communications based on resource-intensity (e.g. social media vs. press releases) to ensure a steady stream of engagement.	**UNDER REVIEW**
12. Collaborate with relevant external organisations to: o enhance the reach and impact of communications activities, making use of existing content already in place, for example the videos from the manufacturing hub projects. o Increase our communication activities to engage the LMIC research community ahead of future competitions.	**IN PROGRESS**
13. Increase engagement with the World Health Organization R&D blueprint teams to inform project strategy and prevent duplication of work will be a priority for 2019/20.	**UNDER REVIEW**

Key successes

Key achievements include:

- Two vaccine platform technologies whose development has been supported by the UKVN against UKVN priority pathogens, a self-amplifying RNA platform (Imperial College) and a chimpanzee adenovirus vaccine vector (ChAdOx, University of Oxford), have been utilised by these institutions to develop the current leading UK COVID-19 vaccine candidates.

- An electronic data capture kit for use in epidemics, that was developed by a project supported under the 'Epidemiology for vaccinology' competition, was successfully utilised in the 2018-2020 outbreaks of Ebola in the Democratic Republic of the Congo to collect, manage and coordinate data. It is estimated to have removed the need to handle 15 million pieces of paper and hundreds of thousands of data-clerk/analyst hours during the North Kivu and Ituri outbreak.

- The UKVN project team initiated and provided significant support to cross government effort to rapidly launch a COVID-19 research call, including vaccine research, in February/March 2020. This utilised strong relationships that had been built through joint working on the UKVN and associated projects.

- Funded projects have successfully completed phase 1 clinical trials for a Rift Valley Fever vaccine in goats and sheep and a Chikungunya vaccine in humans.

- The Future Vaccine Manufacturing Research Hub successfully delivered a Supply Chain Workshop for members of the Developing Countries Vaccine Manufacturers Network (DCVMN) in Hanoi, Vietnam. The workshop focused on solutions to vaccine supply chain issues and was attended by over 50 delegates from vaccine manufacturing companies in 9 countries.

- The UKVN project team have effectively managed the UK governments' relationship with a key stakeholder, CEPI. This has ensured DHSC's voice is effectively heard in key CEPI fora and strengthened alignment on technical priorities across the UKVN and CEPI vaccine R&D portfolios. Multiple vaccine platform technologies supported by the UKVN have been picked up by CEPI for continued development, demonstrating complementarity of these two funding portfolios. This ongoing relationship with CEPI, as an investor and as a technical stakeholder, has subsequently facilitated the close working between the UK and CEPI with respect to COVID19.

- Publication of two academic manuscripts from UKVN working groups. One described the process used to identify UKVN priority pathogens and clinical progress in developing vaccines for these diseases. The second describes a policy tool developed by the UKVN, a veterinary vaccine development process map.

- A successful engagement event was held in February 2020 ("The UKVN 3 years in: progress, challenges and routes to impact") for UKVN funded projects and vaccine development stakeholders. Over 70 attendees joined the event with sessions focused on lessons learned and networks that could support projects to overcome challenges in 4 key areas: Vaccine manufacturing, regulation, getting vaccines to market and establishing effective collaborations.

- Successful delivery of a UKVN meeting in December 2019, which was chaired by the Chief Medical Officer and attended by over 30 network members and stakeholders. Discussions focused on what role the UKVN can play in providing non-financial support to vaccine development projects and how current and future activities can take a more 'end-to-end' approach to vaccine development.

Project Management

Delivery assessment for reporting year: Amber/Green

Changed since last year: No

1. Evidence of managing the delivery of project

Quarter 1: Amber/Green

Quarter 2: Amber/Green

Quarter 3: Amber/Green

Quarter 4: Amber

Overall delivery RAG rating over the reporting period: **Amber/Green**

In 2019/20, the project team shifted its focus from finalising the setup of the UKVN project research portfolio and associated project management processes, to managing the delivery of an established research portfolio. Overall, the project is delivering well with benefits already being realised from project outputs – this demonstrates significant success given the widely acknowledged lag phase between set up and benefits realisation of early-stage scientific R&D projects.

The project team and delivery partners have continued to embed changes to internal project processes that were implemented in previous years. The use of delivery partner scorecards was reviewed from the perspectives of both the project team and delivery partners, all agreed these were a useful relationship management tool that should remain in place. Staffing constraints in the project team continue to pose a challenge and have meant that some project processes e.g. scorecards and project progress reporting do not always happen at the frequency or level of detail desired.

Over the year, 18 projects out of 33 live projects (55%) have encountered challenges that resulted in them requesting changes to the time, budget or scope of their projects. The most common reason for change requests were related to challenges with vaccine manufacturing or unforeseen technical results requiring further investigation or a change of approach. The project team has put into place a systematic review process to handle these project change requests, including independent scientific review where the work to be undertaken differs significantly from that in the original project plan.

During the year, the RAG rating fell from Amber/Green in Q1-Q3 to Amber in Q4. This change reflects decreasing capacity in the project team, delivery partners and UKVN-funded project staff to focus on UKVN project delivery at a time when response activities to the emergence of COVID-19 took priority. This is likely to be an ongoing challenge for the project.

2. Evidence that the project is meeting the agreed milestones and deliverables

The following milestones / deliverables were made by the UKVN project for this reporting year.

Output 1: High quality research that aims to:

- Feed the vaccine development pipeline for 12 priority pathogens
- Test new platforms and technologies to accelerate vaccine development
- Produce processes and products to support vaccine manufacture and delivery in LMICs
- Produce and test epidemiological models for optimal vaccine deployment for UKVN priority pathogens

Output Indicator	Milestones / deliverables	Current status
1.1	Competitions that cover these 4 research areas are run successfully. Year 4 Milestone: Interim/process evaluation shows good implementation of competitions.	COMPLETE
1.2	Number of Projects active and completed. Year 4 Milestone: ≥70 projects contracted (cumulative), c.40 of which complete	COMPLETE
1.3	UKVN funded projects generate outputs	COMPLETE

	Year 4 Milestone: Wide range of high quality outputs generated	
1.4	UK research from across academia and small- to medium-sized enetrprises (SMEs) is accessed to support Project aims. Year 4 Milestone: ≥ 25% active projects are from SMEs	UNDER REVIEW

Output 1 key points:

The UKVN interim evaluation conducted in 2020 found that the UKVN investment has enabled the UK to develop a portfolio of vaccines and vaccine technologies that can be used to respond to current and future pandemics. Over 70 projects have been contracted of which 43 are complete.

During this year, over 200 outputs have been generated by UKVN funded projects. The outputs collected are wide ranging and include journal articles, licensed patents, receipt of follow-on funding, development of novel scientific assays, and participation in school workshops, among others. Outputs are captured through delivery partner mechanisms, such as the Researchfish platform or through quarterly monitoring reports from projects.

At the end of 2019/20 14% of active projects are from SMEs, significantly below the target of 25% or higher. All UKVN project funding is now committed precluding corrective action on this in the current project life cycle. Ahead of any future UKVN funding commitments, the level/relevance of this target should be considered. The impacts recorded for the types of projects and types of organisations supported in the 2016-2020 period should be reviewed in order to design a programme that ensures optimal participation from a variety of research organisations, including those in LMICs and from the private sector.

Output 2: Clear UK vaccine investment strategy contributes to global leadership in this space.

Output Indicator	Milestones / deliverables	Current status
2.1	Use of UKVN policy tools by international stakeholders. Year 4 Milestone: Presentations from international stakeholders at UKVN meeting and further discussions to	COMPLETE

	ensure ongoing UKVN strategy stays relevant and collaboration is encouraged.	
2.1	Use of UKVN policy tools by international stakeholders. Year 4 Milestone: Presentation of UKVN working group outputs at 2 international meetings.	IN PROGRESS
2.1	Use of UKVN policy tools by international stakeholders. Year 4 Milestone: Statistics from website show 20% increase in visits from 2018 level.	COMPLETE
2.2	UK Vaccine Network project funded research supports the development of collaborations between LMIC and UK researchers and organisations. Year 4 Milestone: ≥20% of entire portfolio has active collaborations with LMIC-based researchers or organisations.	COMPLETE
2.3	Findings of UKVN project funded research are disseminated to non-academic audiences, including public health practitioners and the public. Year 4 Milestone: ≥ 20 vaccine relevant GHS tweets/retweets	IN PROGRESS
2.3	Findings of UKVN project funded research are disseminated to non-academic audiences, including public health practitioners and the public. Year 4 Milestone: ≥ 3 case studies on website	IN PROGRESS
2.3	Findings of UKVN project funded research are disseminated to non-academic audiences, including public health practitioners and the public. Year 4 Milestone: Process developed to ensure key project findings are captured by DHSC, including negative results, to inform future research spending programmes and avoid duplication of research.	IN PROGRESS

2.4	UKVN strategy clear and communicated to research community and other stakeholders. Year 4 Milestone: UKVN meeting includes key stakeholders, including other funders and industry.	COMPLETE
2.4	UKVN strategy clear and communicated to research community and other stakeholders. Year 4 Milestone: Meetings held with other vaccine R&D funders and vaccine access/ deployment stakeholders to develop a potential pathway for successful projects to reach market. This is tested with UK Vaccine Network.	IN PROGRESS

Output 2 key points:

International stakeholders presented and engaged in constructive discussion during the UKVN meeting in December 2019 and also in the UKVN event held in February 2020. These events have increased awareness of the UKVN project and have encouraged a collaborative approach to future design questions. However, UKVN working group outputs have not been presented at international meetings and this is something that should be taken forward in the 2020/21 communications strategy. Although not captured as a log frame indicator, the policy tools generated by UKVN working groups have been effectively used in briefing ministers and key stakeholders when planning vaccine response strategies to COVID-19. This demonstrates the value of the UKVN work to support epidemic preparedness. Visits to the UKRI webpage hosting UKVN policy tools increased by 26% in 2019/20 compared to 2018/19. Data indicate that website visits will more than double during 2020/21. This is likely to reflect a general increased interest in vaccines as a result of the COVID-19 pandemic and presents an opportunity for the UKVN team to engage with a new and expanded audience.

Twenty-nine percent of active projects have a LMIC collaboration. To increase the benefits realisation of UKVN projects in LMICs the number and strength of collaborations between UK based UKVN projects and LMIC institutions should be increased in future versions of the project. We will work with the UKVN expert group, stakeholders and other funders to set an appropriate increased target for this indicator. An increase in LMIC collaborations could be implemented by making LMIC collaborations a pre-requisite of UKVN funding in the next spending review and working with delivery partners who proactively reach out to LMIC institutions.

Twelve vaccine relevant tweets/re-tweets were posted this year, short of the target of >20. The twitter account has been dormant for parts of this year due to the pre-election period and advice to limit pro-active communications activity from the programme during the initial phase of the COVID-19 pandemic – these restrictions and limited staff capacity have hampered activity in this area. Three project case studies have been drafted but are not yet published.

Part of the UKVN's project change approval procedure requires projects to capture lessons learned and explain how they will disseminate these learnings with the community. Similarly, for some delivery partners, end of project reports contain a section to identify lessons learned. Securing engagement from projects with these questions has proved challenging at times. As the UKVN project nears its end, it is important these learnings are captured and disseminated to the research community, to help increase the knowledge base of what works and what doesn't, both on technical questions and on project management. The UKVN project should develop and use an issues log and lessons learned log.

Meetings have been held with vaccine R&D funders and other stakeholders to discuss a potential pathway for successful projects to reach market. A review of the current status of the late stage vaccine development space has been completed to identify how the UKVN could continue to contribute in this space. These conversations are ongoing ahead of planning for the next government spending review. A strong relationship between the UKVN project team and CEPI has continued to develop and will be important for the UKVN to maximise future impact in the global vaccine development space. Maintaining strong relationships with CEPI and other international stakeholders, such as the WHO R&D blueprint, will be crucial to ensure the UKVN responds appropriately to the ongoing changes in the international vaccine landscape in response to COVID-19.

Output 3: Effective management, governance and oversight of the UKVN Project.

Output Indicator	Milestones / deliverables	Current status
3.1	Project budget is fully committed and investments represent Value for Money (VfM). Year 4 Milestone: £25m 19/20 budget spent	UNDER REVIEW
3.2	Project delivery approach allows competitions to be delivered to timelines and delivery risks are identified and managed.	COMPLETE

	Year 4 Milestone: All competitions delivered.	
3.2	Project delivery approach allows competitions to be delivered to timelines and delivery risks are identified and managed. Year 4 Milestone: Quarterly Project Delivery Boards and delivery partner performance management process show effective risk management.	COMPLETE

Output 3 key points:

£22,319,420 of £25,000,000 2019/20 project budget was spent. Underspend against project budget was due to several factors including slippage of spend into the next financial year as a result of project extensions, a contamination event at a manufacturing facility used by several projects and cessation/delays of project activities as COVID-19 emerged in Q4. All UKVN competitions have been delivered.

3. Evidence of Risk Management

The following risks were identified by the UKVN Project for this reporting year.

	Risk	**Mitigation Actions**	**RAG rating**	**Current Status / Update**
1	Risk: Continuing changes in project forecasts results in increased funding pressure in future years and underspending against this year's HMT ODA target. Cause: Funding profiles provided by research projects	Close relationships with delivery partners so potential changes in forecasts are identified early. Standing finance agenda item on Project Delivery Board. Quarterly finance meetings with Innovate UK finance business	Red	Continues to present a significant risk to the project. GHS financial lead and UKVN project team continue to pro-actively monitor and risk-adjust financial forecasts. Risk exacerbated towards year end due to pausing/cessation of UKVN-funded projects

	and delivery partners quickly become inaccurate due to the uncertainty of scientific research progression and this prevents DHSC accurately predicting portfolio spend. Effect: Actual spend by projects is lower than the forecasts from delivery partners. This results in increased funding pressure in future years, as well as a failure to meet the current year ODA target. Impact: Reputational risk for Global Health Security (GHS) programme and DHSC, possible reductions in future funding.	partner (largest spend through Innovate). Work closely with the GHS finance lead, to monitor forecasts and produce adjusted profiles to cover different scenarios. COVID-19 scope changes implemented across the portfolio. Active monitoring of COVID-19 impact on UKVN programme delivery.		as a result of the COVID-19 pandemic.
2	Risk: Public and political support for UKVN damaged by unclear results or allegations of poor aid effectiveness. Cause: External challenge from media or organisations Effect: Lack of understanding or	Preparation or resources to respond quickly and accurately to allegations. Proactive sharing of good news stories via twitter feed. GHS communications lead in place and engaged in research comms.	Amber/Red	This is an ongoing risk for the project. Capacity in the project team and the COVID-19 pandemic have limited pro-active communication outputs. The impact of UKVN funding in laying groundwork for COVID19 vaccine efforts and wider project impacts seen this year demonstrates UKVN value. However, team capacity to tell this story has been limited.

	negative sentiment to UKVN project. Impact: Compromise of programme delivery and lack of appetite to consider further funding	Case studies to demonstrate positive impact of the UKVN.		
3	Risk: HMG /DHSC response to COVID-19 outbreak requires additional work from UKVN team and/or temporary redeployment of UKVN team members Cause: COVID-19 outbreak Effect: DHSC staff reallocated and UKVN project under-resourced. Impact: Performance issues with programme, missing key milestones, delays in decision making.	Regular prioritisation exercise to identify what activity should be stopped if team resources are reduced. Organise and run training to build wider resilience in the GHS preparedness team. Ensure periods of annual leave don't overlap.	Amber/Red	This risk materialised into an issue during Q4 due to redployment of UKVN team members.

Summary of risks that have materialised into issues

During Q4 the risk of UKVN project staff capacity being required for COVID-19 pandemic response work moved from a risk to an issue. The team led the delivery of a COVID-19 rapid research call for DHSC, placing significant additional pressures on the team in Feb-March. Later in Q4, the Head of the UKVN (50% of team capacity) was redeployed to another government department for COVID-19 response activities. The team worked to prioritise essential project management functions during this period and reduced activity

relating to proactive communications. This ensured core activity was maintained but resulted in some logframe targets not being met this year. This highlighted a significant vulnerability for a small project team leading delivery of a large project. Successful delivery of the project benefits from detailed understanding of the space in which the UKVN operates and its complex research portfolio, which limits the ability to switch in alternate staff at short notice.

Future action should address cross-training between the two arms of the Preparedness team (the wider team in which the UKVN project team sits), thereby increasing ability for staff to work in an agile manner where need is greatest. This has begun with increased cross working with the Preparedness Policy and Project Officer.

4. Safeguarding

Changes and improvements made in the last year

UKVN project team:

With one year left for the UKVN project, we have decided not to amend the project's existing commercial agreements with partners to include newly developed safeguarding clauses. However, we have led safeguarding discussions with delivery partners and DHSC's safeguarding champion led a teach-in on safeguarding with the UKVN delivery partners. Delivery partners agreed to feed back if there were any projects or areas of the portfolio that presented a particular safeguarding risk and to also actively remind partners about the need to report any safeguarding allegations to the department as soon as these were raised. Future UKVN contracts will include the safeguarding clauses.

Delivery partner updates:

UKRI

UKRI has recently launched a new safeguarding policy and DHSC has been closely working with them on this to ensure, where possible, consistency and alignment around our expectations of the academic community. This is a robust and wide-reaching policy, that covers bullying and harassment, as well as sexual exploitation, abuse and harassment, and will apply to both their ODA-funded and domestic research awards. UKRI recognise that partners will need some time to embed these requirements and will include a clause to their grant Terms and Conditions expecting research contractors to comply with the new safeguarding policy from April 2021.

As joint funders on a number of ODA projects, DHSC has been working closely with UKRI on risk and assurance issues more broadly. This has involved collaborating on research application forms, due diligence and assurance processes. We are currently establishing

an agreement that will allow more systematic flows of assurance information between our two organisations. Through this collaboration, we have insight into how UKRI manage the risk of safeguarding through their existing processes and how this will be strengthened moving forward, particularly through regular exchanges of any safeguarding risks and concerns between our two organisations.

NIHR

DHSC safeguarding leads have been working closely with colleagues in the NIHR co-ordinating centres to embed a robust approach to managing safeguarding risks and issues in the ODA space. Following appointment of an ODA assurance lead, NIHR has strengthened due diligence processes, ensuring safeguarding is appropriately covered and action recommended, as appropriate, to strengthen research contractors' approach. Safeguarding is also considered as part of the NIHR annual funding reviews where the organisation is in receipt of ODA funding. NIHR has built in sufficient clauses on safeguarding to its ODA contract template and is currently developing guidance for research organisations on how they can best evidence compliance with the safeguarding standards.

Safeguarding risks that have arisen during the reporting year

UKVN project delivery partners have confirmed that no safeguarding issues/cases have been reported to them for UKVN-funded projects. Delivery partners have not flagged any safeguarding risks or concerns to DHSC. Future actions should continue to ensure greater understanding of safeguarding issues and processes amongst the UKVN project team, delivery partners and UKVN-funded projects

Summary of project management recommendations for improvement

- The impacts recorded for the types of projects and types of organisations supported in the 2016-2020 period should be reviewed in order to design a programme that ensures optimal participation from different research agencies, including SMEs and organisations in LMICs.
- UKVN working group outputs have not been presented at international meetings and this is something that should be taken forward in the 2020/21 communications strategy.
- LMIC collaborations should be a pre-requisite of a proportion of UKVN funding in the future.

- UKVN case studies should be published.

- Increase UKVN team resilience by building capacity for agile working across the Preparedness and the wider GHS team. An increased team capacity should also be considered as part of the design of the future project, including joint posts with the GHS partner R&D project, GAMRIF.

- UKVN project team and delivery partners to continue to embed safeguarding considerations in their ways of working. To assist this, delivery partner and funded research staff should be encouraged to watch UKCDR's webinar on 'Preventing Harm in Research: Safeguarding in International Development' to increase their understanding of this issue.

Finance

Delivery confidence assessment for reporting year: Amber

Changed since last year: Yes

5. How is the funding being used?

Annual summary

Total annual budget for this reporting year £25,000,000

Total annual spend for reporting year £22,319,420

Spend against budget and forecast

Following an internal risk-adjustment midway through the reporting year, the UKVN project had a budget of £25m but by the end of the year was not forecasting to fully spend this. The underspend, £0.89m of budget was repurposed at year end to fund other ODA activities across the GHS Programme – with the UKVN project forecasting to spend £24.11m by end 2019/20.

UKVN project spend against the expected £24.1m is currently almost £2m lower - with a preliminary final spend amount of £22.3m now anticipated. There are still £0.5m of accruals outstanding from 2019/20 however, so the final spend position is yet to be confirmed.

The underspend against 2019/20 accruals submitted was:

- £0.3m by the Clinical Vaccine Development Competition projects (managed by Innovate UK);

- £0.9m by the Preclinical Vaccine Development Competition projects (managed by Innovate UK); and

- £0.6m by the NIHR NETSCC managed projects.

The EPSRC and BBSRC managed projects were paid on a set payment schedule during 2019/20, and as such there was no variance against this to report. These payment schedules will be reviewed in August 2020 in line with the agreements.

Changes to the financial and/or spending plans that were in place at the start of the reporting period

At the beginning of the financial year, the UKVN project was forecasting a significant overspend against the 2019/20 budget, of £7.9m. Roughly half of this overspend was due to a projected overspend by Innovate UK projects in this period, and a meeting was subsequently arranged with Innovate UK to discuss this, This resulted in the projected overspend being reduced to £5.1m overall across the UKVN research portfolio –with the project initially forecasting a spend of £30.1m against the £25m budget. This level of over-profiling (20%) is recommended by the GHS finance manager for research projects given the known positivity bias in research forecasts.

Forecasts remained fairly consistent for the first part of the financial year, however, with an overspend continuing to be forecast. There was sufficient underspend across the GHS Programme to fund this if additional funding was required. However, project leads and delivery partners alike anticipated that activity and related spend might slip into 2020/21.

Around September 2019, a manufacturing issue resulted in a significant reduction in forecasts of approximately £3m, due to a contamination issue at a manufacturing facility used by a number of projects in the portfolio. The eventual reduction in spend relating to this issue was lower than anticipated (approx. £1.8m). A meeting was also held with Innovate UK in October 2019 to discuss forecasting issues and to explore streamlining of internal Innovate processes with DHSC requirements.

During the second half of the financial year there was a further significant reduction in forecasts, following an internal risk-adjustment by the GHS team, down to £25.7m by December 2019 (£29.9m forecast prior to internal risk-adjustment).

Forecasts continued to reduce during the final quarter of 2019/20, with non-risk-adjusted forecasts dropping by over £3m to £26.6m. Part of this related to Q3 spend, which was lower than anticipated for a number of projects. The remaining £2m reduction in forecasts related to Innovate UK managed projects anticipating a lower spend in 2019/20 –this was subsequently reviewed with Innovate UK to determine the overall impact of this reduction on both the 2019/20 and 2020/21 financial year budgets.

A number of project change requests were received towards the latter part of the financial year which impacted on both project timelines and finances. Notably, there were originally a number of projects due to finish in summer 2020 but the majority of these were extended to March 2021 due to impacts of COVID-19 on planned work. This resulted in a final

projected spend for 2019/20 being £26.1m by delivery partners –this was scrutinised by the project leads and a final accrued position of £24.1m was submitted at year-end following a number of risk-adjustments applied to the forecasts based on project progress and further anticipated slippage into 2020/21.

The progression of project forecasts over the year demonstrates the importance of internal risk adjustment of forecasts received from projects and delivery partners. This is conducted by the GHS finance manager and UKVN project team and is informed by detailed discussions with delivery partners on project progress and external factors that emerge throughout the year.

6. Evidence of ability to administer ODA funding

The ODA eligibility of all expenditure was established at the outset of the programme, and all UKVN project activities commenced pre the 2019/20 financial year. All project scope change requests and project equipment purchase requests (submitted for equipment > £10,000) are assessed for ODA eligibility by the UKVN project team. UKVN project team staff have attended training, provided by DFID, in assessing ODA eligibility.

In the majority of instances, projects provide details of the actual expenditure and revised forecasts quarterly, and these are reviewed with delivery partners. For those projects on set payment schedules, progress reports are submitted to the project lead and reconciliation of spend will take place as outlined in the respective agreements.

There was a process change with Innovate UK financial reporting following a new finance lead being appointed into post. A consultation was held with during Q1 2019/20 to discuss increased alignment of Innovate UK financial reporting with DHSC requirements. This resulted in increased information being provided on expenditure and forecasts for each project, as well as a greater level of detail on the status of individual claims. Finance meetings have continued with Innovate UK on a quarterly basis, to review spend against forecasts and changes in forecasts, and to address any queries with the data. This detailed information exchange has helped to inform risk adjustment of financial data.

ODA Reporting: The UKVN project complies with the requirements to report ODA funding to the Organisation for Economic Co-operation and Development (OECD) in line with OECD Development Assistance Committee (DAC) Directives, via the DHSC Departmental parent and DFID. The Department completes an annual return of all its ODA activities and expenditure to confirm that all spend is untied and meets ODA eligibility criteria.

7. Evidence of activities undertaken to meet IATI transparency standards

Self-assessed score against the IATI transparency standards

80 – 100% (Very good)

Steps taken to ensure transparency of activities

Over this reporting period the UKVN project has provided descriptive data for all activities alongside key supporting documentation required by IATI to be transparent. This data has supported the Department to score 82.1% in the recent Publish What You Fund (PWYF) assessment against the Aid Transparency Index – resulting in DHSC achieving 'Very Good' rating, second only to DFID, so this is a huge achievement for DHSC over such a short space of time.

The team are committed to maintaining and updating the data published to IATI to ensure this remains accurate and transparent. The GHS programme has put in place a monthly publication timetable for 2020 for all financial transactions, which will enable the Department to be scored 100% against each of the 35 IATI indicators. In 2019, publication of transactions was on a quarterly basis, which limited the overall score attainable to 95% against each of indicator. All projects and their activities will continue to be routinely reviewed each quarter, to ensure any new activity or project changes are captured.

One recommendation from the PWYF assessment was to prioritise improving the quality and amount of performance data, particularly results or shared learning, so this will be a key focus in the 2020/21 financial year

8. Evidence of Value for Money (VfM)

Economy (minimising the cost of resources used or required inputs)

The aim of the project is to develop vaccines against key priority infectious diseases and support a broader range of vaccine platform and vaccine manufacturing technologies. This research would increase the ability of the UK and international community to respond to emerging infectious disease outbreaks.

To achieve these objectives, the project sought to invest in a number of key areas:

- Developing candidate vaccines for known priority infectious diseases
- Developing Vaccine Platform Technologies to improve the quality of vaccines and the speed with which new vaccines can be developed to combat an emerging threat
- Developing Vaccine Manufacturing Technology to allow for vaccines to be more efficiently and effectively manufactured

In developing the options and evidence base for delivery, the DHSC core team consulted with a broad range of partners with relevant experience. Questions focussed on how to secure maximum impact for investment; governance; competition mechanisms; competition management; investment oversight and delivery, and a range of other pertinent issues. This consultation ensured that leading experts and experience was drawn on to ensure the programme could be conducted as economically as possible.

Following these consultations, DHSC set the strategic direction and priorities for this investment but, to increase the economy of the programme, sought delivery partners to conduct the calls for proposals and manage the resulting projects. Research funding agencies with specific subject matter expertise, relationships with research community and experience of running complex technical funding competitions in relevant areas were selected as delivery partners. This ensured that the competitions could be delivered effectively but without the high overhead costs of establishing new processes and teams.

Efficiency (the relationship between the output from goods or services and the resources to produce them)

The following actions have been carried out to ensure the UKVN project is run efficiently:

- DHSC as the Department responsible for project expenditure has oversight of how UKVN project budget is spent and queries efficiency of spend where relevant. For example, the UKVN project team ensures that equipment purchases by projects (>

£10,000) are justified and that alternative procurement options have been considered.

- Expert research funding agencies manage the delivery of UKVN projects. As these organisations have the relevant expertise and processes in place for administering research funding, this offers an efficiency saving over the alternative of in-sourcing these expertise and processes at DHSC from scratch.

- The UKVN project team maintains regular engagement with other vaccine R&D funders e.g. CEPI, the Wellcome Trust, DFID, to ensure that current and future UKVN project investment is complementary to, rather than duplicative of, other funding in this space.

- The UKVN project team encourages the sharing of learning amongst UKVN-funded projects, delivery partners and the project team. The aim being that if projects learn from pitfalls others have fallen into, this will save effort, time and money, and ultimately UKVN investment in the future. One example of this is the UKVN-wide event delivered in February 2020. This event was designed to showcase the challenges encountered by projects within the portfolio, how the research teams overcame these and what advice they would give to other projects to avoid the same problems occurring. The event was well attended, and the key learnings are summarised in section 14.

The development of a single epidemic infectious disease vaccine from preclinical trials through to the end of Phase 2a is estimated to cost up to £52 million. In this context and given a total UKVN project budget of £110 million, key project outputs to date indicate that UKVN investment represents efficient use of funds.

Effectiveness (the relationship between the intended and actual results of public spending i.e. outcomes)

Vaccines are widely acknowledged as a key means through which to prevent morbidity and mortality from infectious diseases. Recently, this has been further highlighted by the huge global investments in COVID-19 vaccine development. The effective deployment of vaccines has, particularly in LMIC settings, been shown on numerous occasions to be a highly effective intervention, in terms of their health impact, cost-effectiveness and broader economic benefits.

Infectious disease epidemics are common, particularly in some low-income settings. When the UKVN project was established only 2 of the 12 diseases which the UKVN expert group prioritised as having the most significant epidemic potential, had vaccines that had entered human trials. As of 2019/20, 11 of the 12 UKVN priority pathogens have one or more vaccine candidates in clinical development. UKVN investment has made a significant

contribution to this change, for example, UKVN funding accounts for a high percentage of global vaccine development projects for hantavirus, Rift Valley Fever, Crimean Congo Haemorrhagic Fever and Q Fever.

During the recent independent evaluation of the UKVN project, all interview participants commented on the importance of having the UKVN project in place prior to the COVID-19 pandemic, highlighting the clear role it has played in the UK's ability to respond rapidly to COVID-19.

Equity (the extent to which services are available to and reach all people that they are intended to – spending fairly. Some people may receive differing levels of service for reasons other than differences in their levels of need)

Despite the significant positive health and economic impacts associated with effective vaccine deployment, the 2013-2015 Ebola outbreak in West Africa illustrated that there was a serious market failure in the development process for vaccines for epidemic diseases such as Ebola. Such diseases often have significant outbreak potential in low-income settings, causing significant mortality and morbidity. Due to the sporadic nature of the outbreaks and the low-income settings in which they take place, there is little or no incentive for industry to invest in such products.

UKVN investment has diversified and progressed vaccine R&D pipelines for UKVN priority diseases. This has effectively increased the likelihood that a safe and effective vaccine product for UKVN priority pathogens will be available for use in LMICs in the future. However, development of a vaccine product is not sufficient to ensure access to that vaccine in LMICs. The two UKVN funded vaccine manufacturing hubs are specifically addressing challenges related to developing vaccines suitable for roll out in LMICs e.g. cold-chain requirements. In addition, projects funded through the 'Epidemiology for vaccinology' research call are using epidemiological modelling to understand how best to deploy vaccines for maximum impact and anthropological research is being conducted to understand how to effectively engage local communities in vaccine deployment during outbreaks.

External Engagement

Delivery confidence assessment for reporting year

Activity areas	RAG rating	Changed since last year (Y/N)
Communications	Amber/Red	Y
Stakeholder engagement	Amber	n/a

Overall RAG rating: Amber

9. Evidence of use and success of the communication strategy

The UKVN project team and GHS communications lead initially developed thinking around a revised communication strategy for this year that would: find different platforms for communications content depending on whether the content was general interest information versus news; work with stakeholders to amplify UKVN-funded project communications content; and, expand the research audience.

Due to project staff turnover, staff capacity and external factors (pre-election period and the COVID-19 pandemic), a formal communications strategy was not put in place this year. Nevertheless, some communications activities have been delivered this year including:

- 12 UKVN related tweets/re-tweets from the GHS twitter account and a UKRI blog, which featured the Future Vaccine Manufacturing Research hub
- Press release announcing DHSC's renewed commitment to CEPI in February 2020
- Delivery of a UKVN project wide event with key stakeholders, and associated communications activities around the event itself
- Continued development of case studies of UKVN projects

10. Evidence of external engagement (other)

The UKVN project team regularly engages with delivery partners through formal structures including a quarterly Project Delivery Board, scorecard conversations and financial meetings. In addition, informal ad-hoc meetings/conversations are held as required.

In December 2019, the project team held a meeting of the UKVN expert group which was well received. The UKVN expert group comprises over 30 experts in vaccine development, or related fields from research institutions, industry and government departments. As preparation for this meeting, one-to-one meetings were held between the UKVN project team and key stakeholders including the MHRA, Wellcome Trust and CEPI. Discussions at the December 2019 meeting of the UKVN focused on: the key challenges the UKVN-funded products would face in reaching the next stage of development and ultimate impact; what role the UKVN could play in providing non-financial support to overcome these challenges and maximise UKVN impact; and how the UKVN can best contribute to the global architecture for end-to-end vaccine development. A number of actions resulted from this meeting, including continuing conversations with key stakeholders and working groups. Due to COVID-19 and reduced team capacity, many of these actions are currently on hold but will be picked up as part of the work to develop plans for the second phase of the UKVN.

The UKVN project team continues to engage with CEPI, a key stakeholder in the area of epidemic vaccines development, through CEPI representation at the UKVN meeting, DHSC's continued position on the CEPI Investors' Council and the UK seat on the CEPI board.

A challenge for the UKVN project has been raising awareness of the project as a singular entity and building a community of practice around this. To address this challenge, an event was held in February 2019 to bring together UKVN funded researchers and key stakeholders. Over 70 attendees joined the event with sessions focused on lessons learned and networks that could support projects to overcome challenges in 4 key areas: Vaccine manufacturing, regulation, getting vaccines to market and establishing effective collaborations. The event was developed in partnership with Innovate UK (who funded the event) and the Knowledge Transfer Network (who delivered the event). The event was well received and should form the building blocks for establishing a community of practice for any future iterations of the UKVN.

Smaller communities of practice exist amongst UKVN funded projects:

- Projects funded through the Epidemiology for Vaccinology research call held a one day event in October 2019 to provide research updates and share learning across the 5 different projects. The UKVN project team attended the event and gave a presentation on the UKVN project.

- The two UKVN-funded manufacturing hubs also hold biannual meetings that the UKVN project team attends. These events are attended by a wide range of hub partners including LMIC organisations involved in vaccine manufacturing and development.

Summary of external engagement recommendations improve the effectiveness of stakeholder and delivery partner engagement

The UKVN project should seek to expand its reach and recognition based on an effective community of practice. A review or opinion piece in an academic journal would raise awareness of the project amongst the research community.

Theory of Change

11. Evidence to show if the Theory of Change (Toc) assumptions remains accurate

Copy of ToC is in the annex

Summary of major changes to ToC in the past year

As a result of recommendations made in the 2018/19 annual review, two assumptions in the ToC have been updated. Assumption 8, around sufficeny of the vaccine pipeline, has been updated to reflect the need for R&D pipelines containing multiple Phase 2 candidates to ensure that one will be effective when deployed. Assumption 9, around the selection of successful phase 2 candiates, was added to reflect the need for phase 2 vaccine candidates to have obtained regulatory approval and be accessible in countries where an outbreak has occurred.

Project outputs generated by the UKVN research portfolio provide evidence that assumptions 3, 4, 5 and 6 are valid. A number of UKVN funded projects have received follow on investment this year providing support to assumption 7.

Experience of vaccine development during the COVID-19 pandemic has illustrated the importance of a diverse vaccine R&D pipeline based on multiple platform technologies. Assumption 8 should be updated to reflect the need for not just multiple phase 2-ready vaccines but for multiple candidates based on an array of platform technologies, striking a balance between proven technologies requiring longer R&D timelines and unproven technologies with potential for rapid deployment.

The current pandemic has likewise shone a light on the importance of global vaccine manufacturing capacity. An additional assumption should be added to reflect that sufficient manufacturing capacity is required for doses to be available in the event of an epidemic.

Where the project is on track to contribute to the expected outcomes and impact

The UKVN project already has, or is on track to, contribute to the 5 outcomes outlined in the ToC:

1. **Protocols and processes for effectively using / trialling vaccines are outbreak ready**

   Epidemiology projects funded through the 'Epidemiology for Vaccinology' research call have contributed to protocols and processes used to trial Ebola vaccines in the 2019

outbreaks in DRC. For example, an electronic data kit was employed in the 2018-2020 DRC Ebola outbreaks to collect, manage and coordinate data and is estimated to have removed the need to handle 15 million pieces of paper and hundreds of thousands of data-clerk/analyst hours during the Kivu outbreak.

2. Licensed or unlicensed (phase II ready) vaccines ready for use or trialling when an outbreak occurs

An analysis of vaccine R&D pipelines for the 12 UKVN priority pathogens has demonstrated that UKVN investment has successfully strengthened R&D vaccine pipelines for these pathogens. The UKVN project has directly invested in 20 projects conducting Phase 1 trials spanning the entire range of UKVN priority pathogens. In time this is expected to result in phase II ready vaccines for some of these pathogens. However, vaccine attrition rates are high and the likelihood of UKVN investment resulting in phase II ready candidates for all priority pathogens is low.

3. New technologies accelerate vaccine response to an unknown pathogen

UKVN investment initially supported the development of the vaccine platform technologies that the 2 leading UK COVID-19 vaccine candidates are based on. This has demonstrated the UKVN project's contribution to accelerating vaccine response to unknown pathogens.

4. Improved infrastructure and products to deliver and support emergency vaccine deployment in LMICs

The UKVN funded manufacturing hubs are contributing to improved infrastructure, networks and products to deliver emergency vaccine deployment in LMICs. For example, the Future Vaccine Manufacturing Research hub will be working with the Ugandan Virus Research Institute (UVRI) to trial a COVID-19 vaccine candidate in Uganda.

5. UK R&D Community is ready and able to support future Public Health Emergencies

Through the COVID-19 pandemic UKVN funded project staff have supported the response to the COVID-19 pandemic. Hence, the UKVN project has contributed to the preparedness of the UK R&D community to support Public Health Emergencies. Similarly, a number of UKVN-funded projects have successfully pivotted to work on COVID-19 vaccines suitable for deployment in LMICs.

Summary of changes recommended to the theory of change

- Assumption 8 should be updated to reflect the likelihood of a phase 2-ready vaccine being affected by not only the number of vaccine candidates in the pipeline but the type and range of vaccine platform technologies they are based on.

- An addition assumption should be added to reflect the requirement for sufficient manufacturing capacity to produce the quantity of doses required for deployment during an epidemic.

Monitoring, evaluation and learning

12. Evidence of evaluation

Overview of evaluation activities that have taken place throughout the review period

Manchester Metropolitan University have recently conducted an independent interim evaluation of the UKVN project. The evaluation gathered evidence from interviews and an online survey with UKVN members, global health funders and UKVN funded project staff. The evaluation assessed how the project is progressing towards four key outputs: high quality research, a clear project investment strategy, supporting UK research and effective governance, as well identifying emerging benefits and key challenges.

The evaluation finds that overall the UKVN project has provided a unique opportunity for the development of a portfolio of vaccines and vaccine technology that can be used to respond to current and future epidemics in LMICs, as well as the potential to contribute to global pandemic preparedness. Project success has included building a collaborative environment to bring together experts, researchers, policy makers, industry, government departments and other organisations through working groups to create a strong vision and strategy for the UKVN project. The funding has facilitated the training of researchers both in the UK and overseas, therefore increasing the global vaccine research workforce. The evaluation found that one clear secondary benefit of the UKVN investments in the 2016-2020 period was the foundation the project provided in vaccine development expertise that allowed a rapid UK response to COVID-19.

The evaluation also identifies a number of key issues and a number of recommendations for the UKVN project. These are outlined below.

Summary of recommendations and key issues that have been raised in the evaluation.

The results of the UKVN interim evaluation described below have only recently become available. The UKVN project team are currently reviewing the identified issues and associated recommendations. Some of the issues and recommendations identified e.g. those referring to UK research funding infrastructure fall outside the direct scope of this project, however, consideration will be given as to how the project team can facilitate these issues being addressed by relevant agencies. For those issues and recommendations falling within the scope of the UKVN project, some relate to the current lifecycle of the project e.g. increasing engagement with the UKVN, whereas others e.g. implementation of an impact strategy, could inform planning for any future versions of the project. The UKVN project team will review and determine the most appropriate response to the findings and recommendations.

Key issues identified in the interim evaluation

Issues within the UKVN project activity:

- Lack of consistency in the management and governance of projects across the UKVN research portfolio
- Project reporting requirements have resulted in a large administrative burden for UKVN funded projects
- Lack of opportunity for others outside of the UKVN to engage and collaborate effectively
- Long gaps between UKVN-funded meetings

Issues which fall outside the scope of the UKVN project:

- Absence of long-term investment in UK vaccine R&D
- Delays to UKVN-funded projects due to reliance on overseas facilities

Recommendations from the interim evaluation

Recommendations for the UKVN project:

- Communication strategies should be reviewed, revised and strengthened to promote engagement and discussions between researchers, UKVN, across UKRI and with other external stakeholders. This should include the sharing learning to reduce waste in the funding system.
- An impact strategy with monitoring activities needs to be implemented at the start of a future programme of work to ensure impacts are routinely captured, including all advocacy and policy work. Project successes and advocacy work should be disseminated widely, both within the UKVN project and externally, to promote the work that is being undertaken. This will help to increase the overall impact of future programmes of work.
- A clear vaccine development pipeline tool with funding attached to specific elements needs to be put in place and promoted to continue and safeguard the investment that has been made in this area. The UKVN project should consider

whether other organisations, such as CEPI, could provide financial support for projects at a certain stage of development.

- There is a need to balance the regional research disparities and work with the wider university research community outside of the ‘golden triangle’ (Oxford, Cambridge and London) in terms of promotion and dissemination of funding calls, staff capacity and development, and access to resources.

- The UKVN project needs to consider how it will provide support for patents and intellectual property rights to safeguard UK vaccine research for future licencing. This will be important when the UK has left the European Union.

Recommendations which fall outside the direct control of the UKVN project and will require wider discussion:

- Consideration should be given to having a longer study period that is fully funded. A minimum five-year study period is required to yield better research results and impacts.

  As part of the next phase of work, consideration should be given to initiate an independent vaccine development institute in the UK that is not influenced by the major vaccine companies. This could provide funding to facilitate further collaborations with synergistic technology and product offerings to create new products that would surpass the capabilities of the major vaccine companies which could then be licenced.

13. Evidence of monitoring

Summary of monitoring activities that have taken place throughout the review period.

UKVN project progress is monitored through the following ongoing activities:

- Quarterly highlight reports to the GHS programme board

- Quarterly project delivery boards

- Annual monitoring of progress against log frame indicators

- UKVN delivery partners have a variety of different mechanisms in place to monitor project progress. Written project progress reports are submitted to DHSC either quarterly or biannually, depending on the delivery partner.

Summary of major changes to the logframe in the past year

Previously, the UKVN project sought to measure the quality of research produced by UKVN funded projects through monitoring:

- the number of publications
- the proportion of projects receiving follow on commitments
- the number of non-academic impacts

However, consultation with project delivery partners and monitoring and evaluation colleagues in DHSC and UKRI, highlighted that such targets, when applied retrospectively rather than at project outset, may be harmful and detract from ultimate product development aims. In addition, using indicators traditionally used for 'blue sky' research runs the risk of not capturing outputs associated with R&D product development and applied research. Therefore, these output indicators were consolidated into a single indicator to capture a wide range of project outputs. This entire process was done alongside the Global AMR Innovations Fund project in GHS and is aligned with data collected by the National Institute for Health Research to be wide ranging and representative of numerous knowledge translation and product development outcomes.

14. Evidence of learning

Summary of learning activities that have taken place throughout the review period

The UKVN event held in February 2020 offered an opportunity for the UKVN project team to learn from the experiences of UKVN funded projects and stakeholders, and also for the funded projects to learn from one another. Key lessons identified are summarised below.

Lessons identified for the UKVN project team:

- The UKVN should consider running a Good Manufacturing Practice workshop, in collaboration with others.
- Improved co-operation between regulatory agencies including the environment, food and medicines (human and animal) regulators is required.

- Post-award engagement and support from funders are vital to follow up on successful projects.

- Continuous funding and support of existing funding networks may be preferable over the creation of new networks.

- Funders should engage with industry at the point at which they are selecting projects. Industry can then provide a view on their interest and strategy so that unfunded projects have a higher chance of being translated in the future.

Lessons identified for early-stage epidemic vaccine R&D. The UKVN project should reflect on these learnings at the design stage of any future iterations of the UKVN project.

- Effective engagement with manufacturing contract research organisations is critical to project success.

- Engage regulatory and manufacturing experts early in the project life cycle.

- Consideration to potential intellectual property issues should be given at the project design stage.

- Construct stability and gene deletion issues can cause significant project delays. Invest time and funds in R&D to mitigate these issues and vaccine developers should ensure the master seed is cloned.

- When conducting clinical trials, regulatory consultants in-country are a valuable resource.

- Engagement with manufacturers in LMICs can be done through the Developing Countries Vaccine Manufactures Network (DCVMN) .

- Important to consider the social aspect of epidemics and vaccine deployment. Anthropologists can collaborate with other disciplines to understand the beneficiaries and the people receiving vaccines.

- There can be barriers to working collaborative projects with LMICs including a disparity of resources and administration and logistics where funding is on a small scale or lasts over a limited time.

Summary of recommendations for evaluation, monitoring and learning activities

- All recommendations from the interim evaluation (listed above) should be reviewed and, where appropriate, implemented in the current programme or incorporated into future project design.

- Lessons learned from the UKVN event held in February 2020 (listed above) should be considered during the design of the next stage of the UKVN project.

Diversity and sustainability

Activities that have taken place to ensure everyone is treated fairly, regardless of gender, gender identity, disability, ethnic origin, religion or belief, sexual orientation, marital status, transgender status, age and nationality

During the organisation of UKVN project events effort was made to achieve diverse representation from attendees and speakers.

During this period, a recruitment process was run for the Global Health Security Vaccines Project Manager position in the UKVN team. This process was conducted following Civil Service recruitment guidelines, including anonymising of initial applications. In future the project team should look to pro-actively champion Diversity and Inclusion (D&I) in their team in line with DHSC's D&I strategy, with delivery partners and within the UKVN-funded projects.

Activities that have taken place to minimise carbon emissions and impact on the environment

The UKVN project team complies with the department's travel policy which aims to reduce carbon emissions. Wherever possible, the team uses public transport to attend meetings and travel to international events is only undertaken when there is a justifiable reason/benefit for the project delivery or objectives.

In future, the UKVN team should influence delivery partners and UKVN funded projects to improve environmental stability. Advanced memorandum of understanding clauses that require partners to take action to minimise carbon emissions should be considered. Environmental impact should also be a factor when assessing equipment purchase requests from projects.

Overall Project Delivery and Recommendations

Overall assessment RAG rating

Activity areas	RAG rating	Has RAG rating change since last annual review?
Project Management	Amber/Green	No
Finance	Amber	Yes
Theory of Change	Green	n/a
External Engagement	Amber	No
Overall Delivery Confidence rating:	**Amber/Green**	**No**

List of Recommendations

Project management

- The impacts recorded for the types of projects and types of organisations supported in the 2016-2020 period should be reviewed in order to design a programme that ensures optimal participation from different research agencies, including SMEs and organisations in LMICs.
- UKVN working group outputs have not been presented at international meetings and this is something that should be taken forward in the 2020/21 communications strategy.
- LMIC collaborations should be a pre-requisite of a proportion of UKVN funding in the future.
- UKVN case studies should be published.

- Increase UKVN team resilience by building capacity for agile working across the Preparedness and the wider GHS team. An increased team capacity should also be considered as part of the design of the future project, including joint posts with the GHS partner R&D project, GAMRIF.

- UKVN project team and delivery partners to continue to embed safeguarding considerations in their ways of working. To assist this, project staff should watch UKCDR's webinar on 'Preventing Harm in Research: Safeguarding in International Development' to increase their understanding of this issue.

Finance

- With the UKVN funded projects nearing their completion, it is recommended that full financial reconciliations are undertaken by EPSRC and BBSRC to ensure that payment schedules can be revised as appropriate in line with project expenditure and updated forecasts.

- A recommendation from the Fraud Risk Assessment completed by the DHSC Anti-Fraud Unit is to introduce an invoice spot-checking process. This will be followed up with delivery partners and implemented in 2020/21.

Theory of Change

- Assumption 8 should be updated to reflect the likelihood of a phase 2-ready vaccine being affected by not only the number of vaccine candidates in the pipeline but the type and range of vaccine platform technologies they are based on

- An addition assumption should be added to reflect the requirement for sufficient manufacturing capacity to produce the quantity of doses required for deployment during an epidemic.

External Engagement

- The UKVN project should seek to expand its reach and recognition based on an effective community of practice. A review or opinion piece in an academic journal would raise awareness of the project amongst the research community.

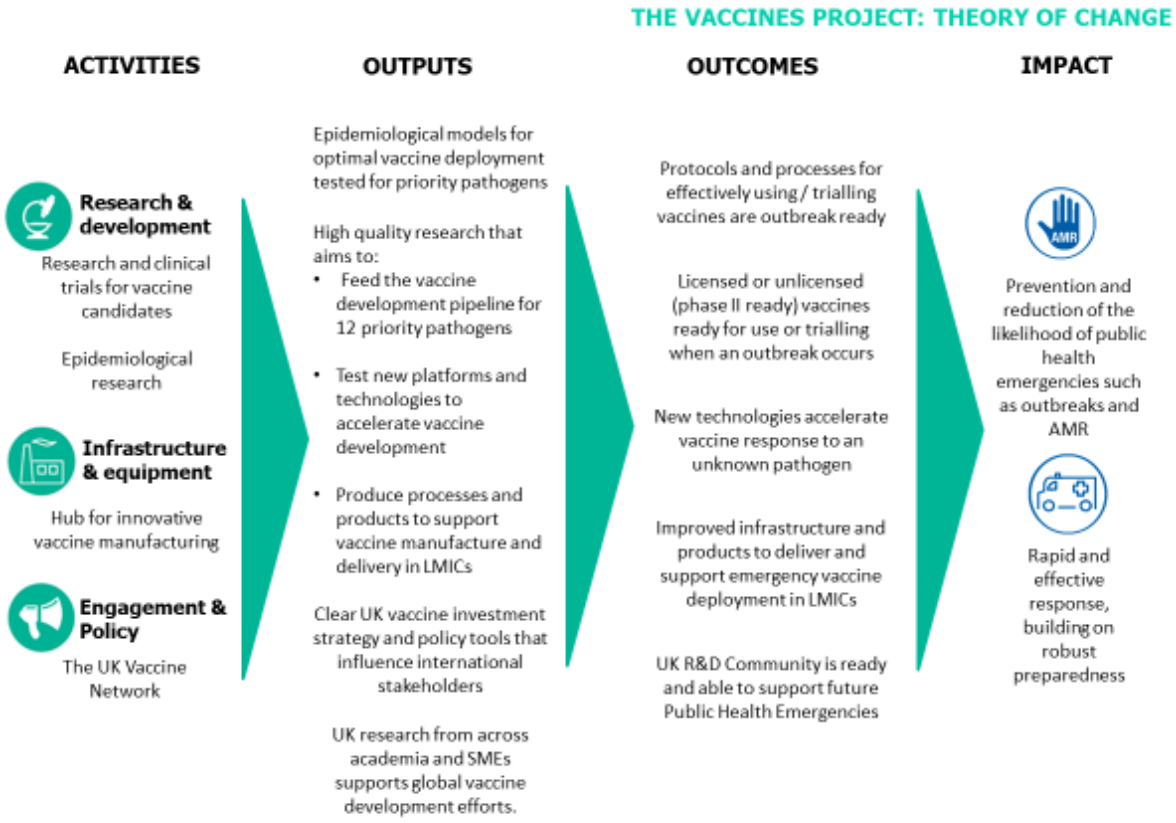
Monitoring, evaluation and learning

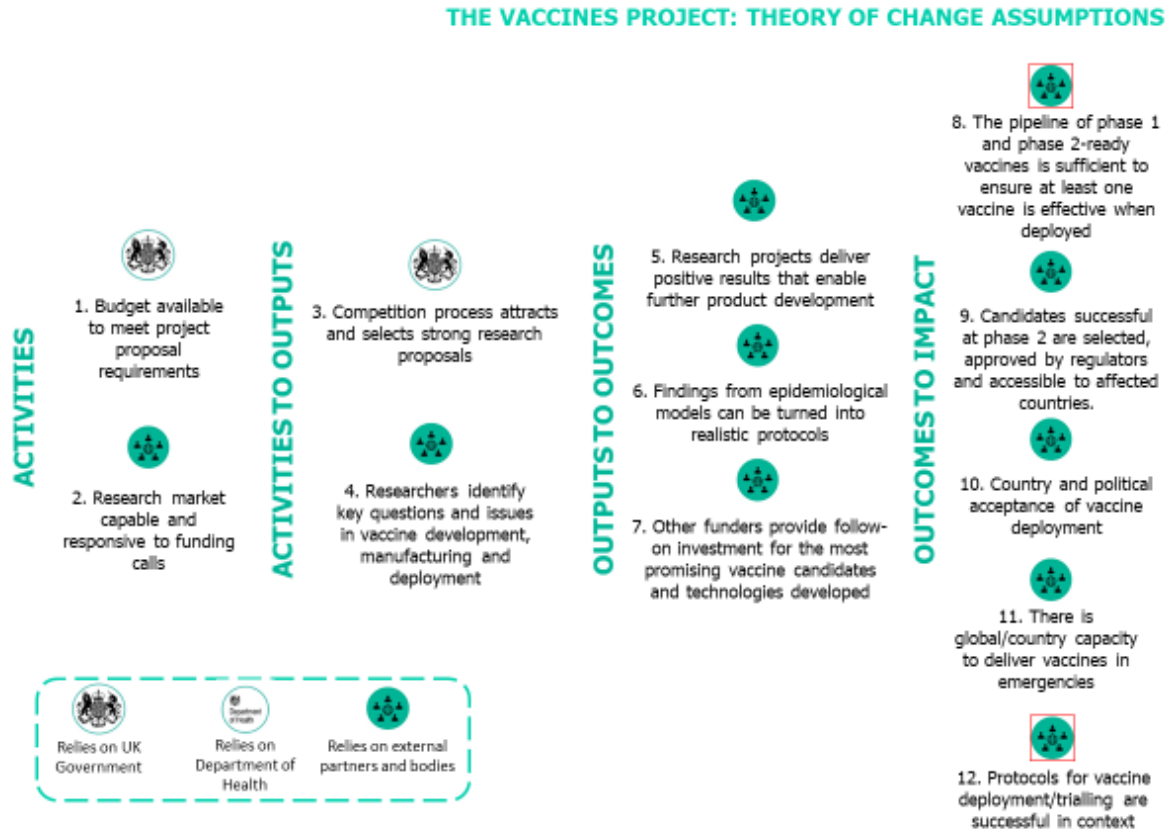
- A recommendation from the Publish What You Fund assessment (December 2019) was to prioritise improving the quality and amount of performance data, particularly results or shared learning.

- All recommendations from the interim evaluation (listed above) should be reviewed and, where appropriate, implemented in the current programme or incorporated into future Project design.

- Lessons learned from the UKVN event held in February 2020 (listed above) should be considered during the design of the next stage of the UKVN project.

Annex 1: UKVN project Theory of Change





Theory of Change (accessible version)

Activities

- Research & development: Research and clinical trials for vaccine candidates; epidemiological research
- Infrastructure & equipment: Hub for innovative vaccine manufacturing
- Engagement & Policy: The UK Vaccine Network expert group

Ouputs

- Epidemiological models for optimal vaccine deployment tested for priority pathogens
- High quality research that aims to:
- Feed the vaccine development pipeline for 12 priority pathogens
- Test new platforms and technologies to accelerate vaccine development
- Produce processes and products to support vaccine manufacture and delivery in LMICs
- Clear UK vaccine investment strategy and policy tools that influence international stakeholders
- UK research from across academia and SMEs supports global vaccine development efforts

Outcomes

- Protocols and processes for effectively using / trialling vaccines are outbreak ready
- Licensed or unlicensed (phase II ready) vaccines ready for use or trialling when an outbreak occurs
- New technologies accelerate vaccine response to an unknown pathogen
- Improved infrastructure and products to deliver and support emergency vaccine deployment in LMICs
- UK R&D Community is ready and able to support future Public Health Emergencies

Impact

- Prevention and reduction of the likelihood of public health emergencies such as outbreaks and AMR
- Rapid and effective response, building on robust preparedness

Assumptions for activities

1. Budget available to meet project proposal requirements
2. Research market capable and responsive to funding calls

Assumptions for activities to outputs

3. Competition process attracts and selects strong research proposals
4. Researchers identify key questions and issues in vaccine development, manufacturing and deployment

Assumptions for outputs to outcomes

5. Research projects deliver positive results that enable further product development
6. Findings from epidemiological models can be turned into realistic protocols
7. Other funders provide follow-on investment for the most promising vaccine candidates and technologies developed

Assumptions for outcomes to impact

8. The pipeline of phase 1 and phase 2-ready vaccines is sufficient to ensure at least one vaccine is effective when deployed
9. Candidates successful at phase 2 are selected, approved by regulators and accessible to affected countries.
10. Country and political acceptance of vaccine deployment
11. There is global/country capacity to deliver vaccines in emergencies
12. Protocols for vaccine deployment/trialling are successful in context

Department of Health and Social Care

International Directorate / Global Health Security Programme / UK Vaccine Network

www.gov.uk/dhsc