Department of Health & Social Care

Annual Review

Global Health Security Programme

Vaccines Project

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Clearance Checklist

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GHS Programme Board sign off	Emma Reed Director of Emergency Planning and Health Protection, DHSC	15/05/2018

Introduction

Outline of programme

In the 2015 spending review the Global Health Security (GHS) team was given £477m of UK Official Development Assistance (ODA) funding to develop projects in and for 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 Vaccines 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 (AMR);
- detect health threats early to save lives; and
- provide rapid and effective response to health threats.

Outline of project in relation to the programme

The Vaccines Project is a £110m ODA-funded project that contributes to the 'prevent and reduce the likelihood of public health emergencies' function of the GHS programme. In particular, the project aims to support the development of new vaccines and vaccine technologies for emergent threats so that outbreaks of such diseases can either be prevented, through proactive vaccination campaigns, or controlled, through quick development of new vaccines and/or responsive vaccination campaigns upon outbreak detection.

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 Scientific Adviser (CSA). The UKVN was established in 2015 in response to the Ebola outbreak and met 6 times across 2015 and 2016. The group identified 12 priority pathogens with epidemic potential in LMICs[1] on which efforts should be focused. The UKVN also advised that investment should be centred on:

- Late-stage preclinical development and early-stage clinical development of vaccine candidates for the priority pathogens[2];
- Development of novel vaccine platforms and manufacturing techniques to:

[1] The 12 priority pathogens are: Chikungunya, Crimean-Congo Haemorrhagic Fever, Ebola, Hantavirus, Lassa, Marburg, Middle-East Respiratory Syndrome, Nipah, Plague, Q Fever, Rift Valley Fever, Zika. Prioritisation criteria included: likelihood of an outbreak; possible severity of an outbreak; and current availability of treatment or vaccine products

[2] For a vaccine to be useful in an emergency outbreak situation it must (as a minimum) have passed safety trials in healthy human volunteers (phase I clinical trials). Therefore progressing vaccine candidates to this point is critical. Taking candidates beyond phase I clinical trials is very expensive and would prevent work taking place on all 12 pathogens.

Outline of project in relation to the programme

- enable vaccines against unknown pathogens to be developed faster
- improve accessibility and delivery of vaccines in LMICs;

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

The project team used this advice to design 7 research competitions. Delivery partners with the required experience and expertise were chosen to deliver these competitions and to manage the resulting research projects. Our delivery partners are:

- the Biotechnology and Biological Sciences Research Council (BBSRC);
- the Engineering and Physical Sciences Research Council (EPSRC);
- Innovate UK; and
- 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 (CCF).

Alongside the delivery of the Vaccines Project the project team are responsible for the continuation of the UKVN, which now holds annual meetings. Importantly, alongside the advice given to the Vaccines Project, the UKVN also has working groups to:

1. maintain the priority pathogen list, updating the list as necessary;
2. understand the vaccine development process from discovery to licensure, and associated bottlenecks;
3. determine the criteria for when investment in the development of a vaccine is the most appropriate response to an outbreak; and,
4. assess existing UK vaccine manufacturing capacity and opportunities to enhance this.

The project team facilitates both the UKVN and its working groups to ensure actions are completed and the group has maximum impact.

This is the first annual review of the Vaccines Project and as such will cover the period from October 2016, when the first research projects began, to March 2018.

Outline summary of project's previous annual review

1	Project Management	N/A
2	Finance	N/A
3	Theory of Change	N/A
4	External Engagement	N/A
5	Overall Delivery Confidence RAG rating from last annual review	N/A

Provide a summary of key points from last annual review.

N/A

Overview of key successes

The Vaccines Project has had a number of successes between October 2016 and March 2018, which has overall been a positive 18 months for the Project.

The key achievements include:

- Two successful UK Vaccine Network meetings, in November 2016 and November 2017, ensuring the project was achieving its strategic aims and allowing discussions on the future of the project.
- Setting up robust project management processes, including establishing the quarterly Project Delivery Board to bring together key partners to improve engagement across partners and share learning.
- Delivering five first-stage research competitions and one second-stage research competition, in partnership with our cross-government partners BBSRC, EPSRC, Innovate UK, NIHR CCF and NIHR NETSCC.
- Establishing a diverse portfolio of 71 research projects, covering all 12 priority pathogens and including pre-clinical and clinical vaccine development and research on associated vaccine technologies and methodologies. In total, £87.7m of the £110m budget has now been committed to support these projects.
- Working closely with delivery partners to support projects and enable utilisation of the full Vaccines Project budget in financial year 2017/2018.
- Increasing stakeholder engagement and communication with stakeholders and the wider public.

1. Project Management

Overall delivery confidence assessment for the management of the project.

Risk Rating: Amber/Green (Medium Low)

The project team has implemented a number of new delivery management approaches and has now achieved a key milestone of delivering the first stage of all 7 of its research competitions. However, there are ongoing risks to project delivery including accuracy of financial forecasting which will continue to be monitored.

Risk revised since last annual review: Yes ☐No ☐ N/A ☒

1.1 Evidence of managing the delivery of the project.

Project delivery's RAG rating from the monthly highlight reports:

Dec 16	Jan 17	Mar 17	Apr 17	Jun 17	Jul 17	Aug 17	Sep 17	Oct 17	Nov 17	Dec 17	Jan 18	Feb 18	Mar 18	Apr 18
A	A	A	A	A/G	A/G	A	A	A	A	A	A	A/G	A/G	G

Overall delivery RAG rating throughout the reporting year:	**A**

Overview of key delivery management approaches.

Vaccines Project team

The project team uses the following delivery management tools:

1. an active risk register, reviewing risks and mitigating actions monthly;
2. a ‘plan on a page’ to cover key pieces of work and deadlines, allowing the team to track major upcoming activity;
3. an overview spreadsheet containing key information on all funded projects that is updated when new projects are funded or when project change requests are granted; and,
4. monthly reporting of key activity to the GHS programme board.

Delivery partners

The progress of individual research projects is monitored by the relevant delivery partner (BBSRC, EPSRC, Innovate UK, NETSCC or CCF). The monitoring framework used differs between delivery partners but as a minimum includes annual progress reports and financial reporting. Throughout the period under review delivery partners have communicated financial information to DHSC each quarter. Monitoring meetings concerning progress of projects have also been carried out regularly with NETSCC throughout this period. Since becoming fully staffed in October 2017, after a 6 month period with reduced capacity, the project team have also established regular communication regarding project progress with Innovate UK (the other delivery partner with active projects). These regular meetings allow the timely identification of issues that could affect project outputs and/or spending profiles. We will look to extend this format to the remaining delivery partners as the research projects they manage become active.

To complement these bilateral engagements we have established a quarterly Project Delivery Board to provide a forum to discuss common issues across delivery partners and to share lessons learned both by the project team and by the delivery partners. The first meeting of this group was held in February 2018 and was used to give delivery partners an overview of the entire Vaccines Project portfolio and the project's financial forecast, and to gain input on the project's developing evaluation strategy.

UK Vaccines Network

The project team organise annual meetings of the UKVN which provide important scientific challenge to the progression of the vaccines project, as well as progressing other elements of UKVN-led work.

1.2 Evidence of meeting milestones/deliverables.

Overview of progress against the milestones/deliverables.

1. High quality, scientifically rigorous competitions that support funding of world leading science, including a broad range of potential projects to invest in. *(Key deliverable from Business Case)*

To date we have held 7 independent funding competitions, through which we have committed over £87.7million of the £110m budget to support 71 projects. The competitions have all been delivered using the well-established competition formats of our delivery partners, which have all included the review of applications by a panel of experts in the field. Of these 7 independent competitions, 5 have been held in the period under review (Oct 2016- 2017/2018)[3]:

- Innovate UK clinical vaccine research competition- £21.3m committed to 7 research projects, which all include clinical trials
- Innovate UK preclinical vaccine research competition- £9.6m committed to 22 research projects[4]
- EPSRC Manufacturing Hub competition- £16.9m committed to establish two Innovative Vaccine Manufacturing Hubs
- BBSRC One Health Vaccine competition- £5.4m awarded to 5 projects which are due to begin in May 2018[5]
- NIHR Epidemiology for Vaccinology competition- up to £5m[6] awarded to 5 projects which are due to begin between April and June 2018

This year the project team have also held a second stage competition for preclinical projects funded through the 2016 Innovate UK vaccine development competition. Through this second stage competition we are supporting the continuation of 4 projects, committing a total of £7.6m.

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[3] The remaining 2 competitions were held earlier in 2016 through Innovate UK and NIHR NETSCC with a total of £23m committed to support 26 projects, including a mixture of pre-clinical and clinical research.

[4] These projects will have an opportunity to apply for further funding through a second stage competition in summer 2018.

[5] Agreement to extend the original £5m budget for this competition to £5.4m was made in April 2018, after the date of this Annual Review, but is reflected here for consistency.

[6] Contract negotiations and decisions of award amounts were ongoing at time of review.

The 71 projects that have been awarded funding include research into all 12 of the priority pathogens and cover a broad range of topics, including: clinical and pre-clinical research to advance promising vaccine candidates; pre-clinical research to develop novel vaccine platforms and improve vaccine formulations and thermostability; and, epidemiological and anthropological work to support vaccine deployment during outbreaks.

The quality of the research resulting from these projects will be assessed as part of the project evaluation, however the presence of a number of world-leading scientists within the successful applicants, and the observation that some project teams are already leveraging further funding (see section 3.1 assumption 7) are both promising signals.

During project inception there was not a formal timetable for completion of competitions. However, a number of the competitions were delayed by the 2017 election, a situation that was then exacerbated by understaffing of the vaccines team. Nevertheless, the completion of all 7 planned competitions is an important milestone for the Vaccines Project, with only delivery of the second-stage of the Innovate UK preclinical competition remaining.

2. Grant/contract agreement signed to an agreed standard. Day to day management of grants/contracts undertaken proficiently, including monitoring of budget commitments. *(Key deliverable from business case)*

We have memorandums of understanding (MOUs) in place with BBSRC, EPSRC and Innovate UK. Our work with the commissioning facilities of NIHR (NETSCC and CCF) is covered by a wider contract which is managed by the Science, Research and Evidence directorate within DHSC.

A combination of research grants (BBSRC and EPSRC) and research contracts (Innovate UK, NETSCC and CCF) have been used for agreements with the successful projects. The project team has worked with the Government Legal Service to ensure that the research contracts, which are based on the delivery partner's standard contracts, are fit for our purposes. In the case of Innovate UK, for example, this resulted in some revisions to their usual template, including inclusion of a DHSC signatory, an ODA eligibility statement and changes to the intellectual property rights (IPR) clause.

DHSC, BBSRC and EPSRC are proactively engaging to ensure all parties have the information they require to demonstrate that grants made by BBSRC and EPSRC on behalf of DHSC meet the required DHSC and Cabinet Office grant standards.

Ongoing grant and contract management is undertaken by our delivery partners. This includes the receipt of financial updates from projects and project update reports at an agreed frequency (quarterly, 6 monthly or annually), dependent on the competition. Financial data are consolidated across the portfolio every quarter by the GHS Finance Lead to identify any potential over- or under-spend of the Vaccines Project budget. Receiving accurate forecasts from projects has been an ongoing challenge for the Project (see section 1.5). However, increased close working between the project team, the GHS Finance Lead and delivery partners, including through the newly established Project Delivery Board, has enabled the Vaccines Project budget to be fully spent in financial year 2017/2018.

3. Delivery of successful UK Vaccines Network meetings

The first UKVN meeting in this reporting period was in November 2016. The meeting was well attended and included discussions on the outputs of the working groups. At this meeting the decision to reduce the frequency of UKVN meetings was taken, as progression of the Vaccines Project meant that currently less strategic advice was needed.

A number of actions from this meeting were taken forward including the online publication of the vaccine development process and decision tree tools produced by working groups 1 and 2 in September 2017 (see section 4.1). However, the delivery of a number of other actions was delayed until the team was fully staffed, in order to prioritise delivery of the planned competitions from April 2017 to September 2017. These actions include production of publications detailing the work of the UKVN to academic journals and the application of the UKVN-developed tools to the projects applying for funding.

A second UKVN meeting took place in November 2017. This was also a successful meeting of the group with Network members commenting that it was an interesting, productive and useful meeting. This was an important success as it is crucial that the continued engagement of the UKVN members is maintained to give an active link between the ongoing project delivery and the scientific expertise. This engagement was considered a significant risk by the team given the reduction in the frequency of UKVN meetings. The project team are working to ensure that the actions from this meeting, including the academic publication of work, are achieved.

1.3 Evidence of managing risks.

1.3a Provide an overview of the management approach to managing risk.

The Vaccines Project team maintain a risk register for the project that is reviewed monthly. Significant risks (with a red RAG status) are escalated to the GHS Programme risk register.

An important role of the newly established Project Delivery Board (see section 1.5) is to identify project management and delivery risks, especially those that may impact more than one delivery partner. The board also acts as a means to reduce delivery risks by sharing learning on the delivery of ODA-funded programmes between partners.

Finally, at a macro level, the project team seeks to reduce risk by obtaining expert advice on key decisions from the DHSC CSA and the UKVN, and by communicating regularly with other key stakeholders in this area such as the Wellcome Trust and the Coalition for Epidemic Preparedness Innovations (CEPI). These conversations work to ensure the project remains relevant in, and responsive to, the wider scientific and funding landscapes.

1.3b Summary of current risks and mitigating actions.

Risk Description	RAG status	Mitigating action	Residual Risk
There is a risk of duplication of work between CEPI, the WHO R&D blueprint, other international funders and the DHSC Vaccines Project. This results in a waste of time and ODA resource.	A	1. Maintain regular communication with key funders such as CEPI, Wellcome and DFID to ensure funding is synergistic not duplicative. 2. Participate in and make use of the ongoing CEPI survey of funders to identify areas that need further investment.	G

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Risk Description	RAG status	Mitigating action	Residual Risk
Individual research projects yield negative results and so do not lead to new vaccine products or technologies for the priority pathogens. This results in the money invested not being able to help prevent future epidemics and the impact of the project is intangible.	G	1. Funding is spread across projects using diverse technologies and scientific techniques. 2. Acceptance that some projects will fail. 3. Work closely with delivery partners to identify and support projects with difficulties to prevent failure due to poor project management.	G
Continuing changes in project forecasts results in increased funding pressure in future years and underspending against this year's HMT ODA target. This carries a reputational risk for DH and possible reduction in funding.	A/R	1. Now vaccines team is fully staffed, work to build relationships with delivery partners so potential changes in forecasts are identified early. 2. Establish a Project Delivery Board to share financial information. 3. Work closely with the GHS finance lead, to monitor forecasts and produce adjusted profiles to cover different scenarios.	A
Impact of UKVN and associated funding programme not recognised.	R	1. Develop and Implement an evaluation strategy for the Vaccines Project, to ensure impacts and areas for improvements are identified. 2. Produce and implement a communications plan for Vaccines Project.	G
Disengagement of UKVN members.	A/G	1. Ensure progression of actions from UKVN meetings. 2. Consider future role of UKVN with input from members to ensure buy-in. 3. Engage network members in the evaluation to ensure that the project evaluation is robust.	A/G

Risk Description	RAG status	Mitigating action	Residual Risk
The project is unable to commit full funding to high quality research projects as the research field becomes saturated from previous competitions and the funding initiatives of other stakeholders, which also increased following the West African Ebola outbreak.	A/R	1. Be flexible to extend/reduce budgets of individual competitions dependent on quality of proposals received so that the best projects are funded across the portfolio. 2. Maintain regular communication with delivery partners and other stakeholders to identify research areas that are either saturated or underinvested.	A/G
UK Research and Innovation (UKRI) will be established in April 2018 and there are likely to be wider corporate changes that will affect BBSRC, EPSRC and Innovate UK. It is not possible to anticipate what effect, if any, these changes will have but it is recognised that they could impact partner's capacity to engage with the Vaccines Project team.	A	1. Monitor UKRI transition process through discussions at the Project Delivery Board and in regular meetings with relevant delivery partners. 2. Work with delivery partners and DHSC lawyers to enable required changes to project contracts or processes.	A/G

1.4. Evidence of delivery partner management

Overview of overall performance of projects stakeholders / delivery partner(s) / supplier(s) or sub-contractor(s).

The project's delivery partners have performed well, as evidenced by the successful delivery of 5 research competitions in the period under review. All delivery partners have significant experience in running competitions and have brought this to bear on the Vaccines Project, with strong review panels and efficient progression from competition opening to grant award.

All 7 core competitions have now been held and have attracted high quality research projects for funding; with one remaining second-stage competition to be held in Q2 2018. This is the case despite the unexpected general election in 2017, which was not accounted for in original project timelines.

Since all posts on the team have been filled, the team have worked to clarify reporting expectations with delivery partners and to establish formal reporting procedures. More information on the approaches taken to further develop performance reporting is in section 1.5.

1.5. Evidence of relationship management.

Overview of risks/issues that relate to stakeholders / delivery partner(s) / supplier(s) or sub-contractor(s).

Delivery partner relationship management

The Vaccines Project was a complex new programme of work for DHSC with research projects spread across a number of delivery partners. The research the Project funds is novel and technically complex and therefore carries a high risk of projects meeting unforeseen obstacles or needing to adapt their research approaches. These factors make accurate forecasting by project leads challenging.

As a result there has been a high degree of uncertainty within the forecasts received from delivery partners for the first 18 months of active research funding. This has been a significant challenge for the project team and resulted in much lower spend than anticipated during 2016/17 (see section 2.2).

Since October 2018, once fully staffed, the project team have prioritised increasing the frequency and consistency of communication with delivery partners who have active projects in a targeted effort to improve project forecasts. This increased communication has allowed the early communication of issues within projects- both scientific and financial- from delivery partners to DHSC and the clearer explanation of the importance of accurate forecasting from DHSC to its partners.

This has resulted in a marked improvement toward the end of financial year 2017/18. For example, actual spend and accruals provided for Q4 2017/18 were largely in-line with the forecasts (in fact – they were exceeded by £0.5m).The team will expand these regular meetings to accommodate all delivery partners as the projects they manage become active.

The Project Delivery Board has also been established to further build relationships, increase opportunities for communication and to establish ways of working between DHSC and its partners going forward. The first meeting had representatives from 4 of the 5 delivery partners and included a session led by the GHS Finance Lead to explain the impact of changing forecasts on the programme. Delivery partners have since requested a version of the paper used in the session to help communicate this message to projects.

Stakeholder relationship management

Carrying out proactive stakeholder engagement is an important mitigating action of the project team to prevent duplication of work by other investors in the field. Since the team has been fully staffed, this has been an active area of work. To date the team have focused on building relationships with key stakeholders, such as the Wellcome Trust and CEPI as well as other teams within DHSC, through regular communications and face-to-face meetings.

The team will now look to engage more widely, particularly focusing on strategic engagement with DFID and the WHO R&D blueprint to ensure there are opportunities for collaboration, to share learning and to identify possible future workstreams.

1.6. Significant changes to assumptions and strategic risk.

There have not been significant changes to the assumptions, project approach or strategic risks identified in the business case at the beginning of the programme. None of the strategic risks have materialised but they do remain on the project risk register with ongoing mitigating actions (see section 1.3b).

1.7. Value for Money.

Overview of how the project demonstrates its realisation of the cost benefit analysis (undertaken during inception).

It is widely accepted that vaccines are an impactful and cost-effective public health intervention in LMICs[7]. Conversely, the economic cost of not acting is high, as demonstrated by the 2014 West African Ebola outbreak which cost >11,000 lives and £2.2bn to GDP of the affected countries[8], as well as significant financial costs to the many other countries involved in responding to the outbreak[9]. If a vaccine had been developed, it may have been possible to contain the outbreak at a lower cost, both to life and the economy. Taken together, this information provides a strong rationale for the project.

In addition, funding this programme of work contributes to the Government Manifesto commitment to "lead a major new global programme to accelerate the development of vaccines and drugs to eliminate the world's deadliest infectious diseases".

A qualitative cost-benefit analysis was undertaken in the project business case to compare the different mechanisms through which the project could be delivered, including in-depth analysis of the critical success criteria of the project.

One of the primary arguments for delivering the project through the different research funding bodies was that these organisations are experts in different areas of research and have extensive experience of running competitions in their given field. This experience and their familiarity with the relevant research community would allow more effective and efficient awards to be made that would provide value for money investments.

In practice, we have seen effective and efficient competitions run which have produced high quality applications. In addition, the project team has seen the positive impact of using a variety of delivery partners with significant subject matter expertise and experience. For example, EPSRC, who are managing the Innovative Vaccines Manufacturing Hub projects, are currently funding other similar hubs and are using this experience to inform the management of these projects.

The benefit of such experienced delivery partners outweighs the additional cost of using multiple partners, as compared to one partner delivering the entire portfolio, which would have allowed DHSC to take advantage of economies of scale when negotiating running costs.

The outcomes of the research projects are not yet known for the majority of the competitions. However, due to the innovative nature of this research all findings, whether positive or negative, are useful. Therefore funding high quality research to inform the field is in itself an important aim of the project.

Summary of project's progress towards last year's issues and recommendations that were made.
N/A

List of Recommendations for reporting year

[7] See for example: Ozawa et al, Cost-effectiveness and economic benefits of vaccines in low and middle income countries: a systematic review, Vaccine, 2012

[8] Guinea, Liberia and Sierra Leone.

[9] For example, the UK Government spent £400 million to help combat the 2014 Ebola outbreak.

List of Recommendations for reporting year
1.1 Invite feedback from delivery partners on our relationship management to identify further improvements. 1.2 Proactively increase engagement with DFID teams and the WHO R&D blueprint teams to inform project strategy and prevent duplication of work. 1.3 Produce a clear milestone delivery plan and log frame for Apr 2018-Mar 2019 to support project progression and aid delivery assessment.

2. Finance

Overall delivery confidence assessment for project's finance.

Risk Rating: Amber/Green (Medium Low)

The Vaccines Project fully utilised its budget in financial year 2017/2018. However, accuracy of financial forecasting for the constituent research projects remains a risk to the project meeting both its budget and the HMT targets in future years. Across the period under review progress has been made towards transparency targets, with further work planned to continue on this trajectory.

Risk reviewed since last annual review: Yes ☐ No ☐ N/A ☒

2.1 Evidence of meeting ODA funding eligibility.

Key points:

ODA eligibility is considered in the Vaccines Project business case, to ensure that the funding provided to the various project streams furthers the sustainable development and welfare of developing countries. Accordingly, the priority pathogens which the Project targets cause diseases found primarily in LMICs. Increasing our ability to combat these diseases through vaccine development will help lessen the cost to life and the economy of future outbreaks in these countries.

The majority of the external organisations with implementing responsibility for the Vaccines Project funds are public sector institutions with experience of overseeing ODA-compliant research on behalf of Government. Similarly, many of the providers who bid for funding are increasingly gaining experience of working on ODA funded programmes. As such, the risk of non-ODA compliance was identified as “Low” in the Project business case.

BBSRC, EPSRC and Innovate UK formally acknowledge that it is the Department’s intention that all monies paid to the successful projects will be properly categorised as ODA by the OECD in the MoUs that are in place. Agreement is in place for them to notify DHSC of any concern it has that monies paid to the successful projects cannot be properly categorised as ODA as soon as reasonably practicable.

Disbursements are made based on the research contract or grant agreed between the Research Funding Agency and the Provider, but include relevant language on the need to ensure spend is ODA compliant and that appropriate data is made available for ODA reporting.

2.2. Evidence of financial year budget.

With respect to project spend by financial year budgets, the Vaccines Project had an underspend of £3.5m against their £10m budget in the 2016/17 financial year. This put increased pressure on the future year budgets as the underspend was returned back to HMT to support other ODA eligible programmes.

However, in 2017/18 the Vaccines Project has exceeded its financial year budget of £25m by just over £2m. This has helped to significantly reduce the overall underspend position for the Vaccines Project, and has supported DHSC to reach its ODA commitment.

2.3. Evidence of meeting the target given by HMT on annual returns.

Delivery partners are aware of the ODA spending target and requirement to report spend on a calendar year basis. In the period covered by this review, Innovate UK and NETSCC have provided financial information – including actual project spend and revised forecasts – on a quarterly basis. This supported the DHSC requirement to complete in-year monitoring returns to DFID/HMT. They also submitted Q3 financial year invoices in early to mid-December for ODA projects, ahead of the HMT deadline of 15 December, which helped contribute to the cross-government commitment to spend 0.7% GNI each calendar year.

The Vaccines Project was a new programme of ODA funded research for DHSC, developed from a standing start in 2016. The initial budget profiles, though based on the best information at the time, were necessarily highly indicative for a new programme. Likewise, the HMT spending target of 90% for the first year of Departmental ODA funding proved overly ambitious for a research based budget, and as a result was subsequently reduced to 85% in the second year of the programme. This updated target of 85% remains difficult for research projects to attain because the majority of project funding is used to pay salary costs and so follows a flat-profile and cannot be compressed into the April-December reporting period. Consequently, the GHS finance lead will be discussing the possibility of a more realistic 75% target for future financial years of this programme with HMT.

With respect to the 2016 and 2017 targets, as the new projects geared up the Vaccines Project achieved 22% against its 90% target in 2016 and 55% (including accruals) against its 85% target in 2017. These lower spends against calendar year profiles for the first 18 months of the project are in large part due to initial optimism bias in setting the original profile. In reality, significant additional time was needed to set up and run the level of high quality research competitions essential to successful delivery; and to provide the time needed to subsequently establish the successful projects, including recruitment of highly skilled technical staff. Both of these steps are necessary to ensure the Vaccines Project funds the best research and achieves value for money. This represents a valuable learning for DHSC for its future management of ODA research projects.

Building on its increasing experience of ODA funding, awareness of research competition management, and through working with HMT to establish a suitable target, the project team will be looking to build on the improvements it made between 2016 and 2017 to meet the targets set in the remaining years of the programme.

2.4 Evidence of progress and actions to meet IATI transparency standards.

Self-assessed score against IATI transparency standards.

0 - 19%	**Very Poor**	☐
20 - 39%	**Poor**	☐
40 - 59%	**Fair**	☒
60 - 79%	**Good**	☐
80 - 100%	**Excellent**	☐

Overview of actions the project has undertaken to meet the IATI transparency standards of 60% target.

Key Points

Finance

As set out in section 2.2, ODA funding was new to DHSC in 2016 and as such the Department as a whole is beginning the process of ensuring it meets IATI transparency standards. As part of this work DHSC is aiming to meet the 'Good' standard (60%-79%) by March 2019.

To move toward this target for the Vaccines Project, the GHS Finance Lead has uploaded information to meet some aspects of the Finance and Budgets, Project Attributes and Joining-up Development Data components of the 2018 Aid Transparency Index Indicators onto a publishing tool called AidStream. This information has been verified by Project Leads, Finance, GHS Communications and the Transparency SRO. This is now ready for publication, and once published will increase the UK Vaccine Network transparency score to 49% overall (through self-evaluation). Publication is expected during w/c 9 April 2018.

Further work will be undertaken in 2018/19 to increase this score further, with a particular focus on publishing business cases, MoUs and other supporting documentation.

Summary of project's progress towards last year's issues and recommendations that were made.
N/A

List of Recommendations for reporting year
2.1 Work closely with delivery partners and in particular the partners for whom expenditure is in the early stages, to ensure that the ODA reporting requirements are well understood.
2.2 Ensure delivery partners provide updates on project progress at agreed intervals, including actual expenditure and revised forecasts, to increase DHSC confidence in the in-year monitoring returns submitted to DFID/HMT.
2.3 Publish documents for the UK Vaccine Network on Gov.UK or an alternative accessible URL to increase the project transparency score. DFID have a list of 12 recommended documents to publish (if available), which include: Business case; Logframe; MoU/MoU amendments; Annual Review; and Evaluation report.
2.4 Encourage delivery partners to attend the DHSC Transparency workshop, which is scheduled to be hosted in early summer 2018, to ensure that they are aware of their transparency requirements.

3. Theory of Change

3.1 Evidence to show project's theory of change assumptions remain accurate.

Overview the project's theory of change assumptions made.

Key points:

The Vaccines Project theory of change (ToC)(Annex A) was updated recently, in line with production of the programme-wide ToC. The assumptions were also reviewed at this time and the accuracy of these updated assumptions is considered below. Due to this recent update, we do not recommend any changes at this time.

1. Budget available to meet project proposal requirements

The Vaccines Project budget has remained fixed since inception of the project, despite a reduction in GNI in 2017/2018. We do not anticipate the budget will change in the course of this SR period, particularly given the funding will soon be fully committed.

2. Research market capable and responsive to funding calls

Following the low application numbers to the recent BBSRC competition (10 applicants were received where BBSRC were expecting c.30) we were concerned that the research market in this field might have become exhausted from previous UKVN calls and other stakeholder initiatives. However, a discussion with academics on the review panel for this competition indicated that this low response was instead due to low awareness of the call amongst the research community (3 of the 5 reviewers stated that they would have applied if they had seen the call), rather than saturation of the research field. The reasons for this low pick-up are being explored with BBSRC, who followed their usual communication strategy for this competition.

3. Competition process attracts and selects strongest research proposals
4. Researchers identify key questions and issues in vaccine development, manufacturing and deployment
5. Research projects deliver positive results that enable further product development
6. Findings from epidemiological models can be turned into realistic protocols

These four assumptions remain reasonable based on the rigorous competition process that our delivery partners apply to ensure the best projects are identified. These processes included a very high calibre of review panel members for each competition who voiced positive views about the strength of the subsequently-funded proposals. Importantly, in three of the competitions run-to-date the review panels took the decision not to commit the full funding available. Demonstrating that they were focused on funding only the highest quality research, rather than being focused on using the available budget.

7. Other funders provide follow-on investment for the vaccine candidates and technologies developed

This assumption remains accurate as we have already seen follow-on investment for two of the projects that were funded through our 2016 Innovate UK competitions:

- The project is funding two projects with Prokarium Ltd, a UK based synthetic biology company, for the preclinical development of an oral Zika Vaccine and the clinical evaluation of an oral plague vaccine. Prokarium announced in February 2018 that they have secured

an additional $10 million investment from Saudi, Swedish and Korean investors for the continued clinical development of their thermostable vaccine platform, expanding the range of diseases to also include Chlamydia, C.difficile and Typhoid.

- The project is funding one project with Austrian Biotech firm Themis for clinical studies of a Zika virus vaccine. Themis announced in March 2018 that they have been awarded $37.5m from CEPI to develop vaccines for both Lassa fever and Middle East respiratory syndrome (MERS) using similar vaccine technology to that which they are developing for the Zika virus vaccine.

8. Phase 2-ready vaccines are effective when deployed
9. Country and political acceptance of vaccine deployment
10. There is global/country capacity to deliver vaccines in emergencies
11. Protocols for vaccine deployment/trialling are successful in context

These final 4 assumptions are much broader and refer to the transition from project outcomes to impact. We feel that assumption 10 is still accurate given the recent signal that the US will continue their support for global health security work, along with other global initiatives.

Global trends on vaccine hesitancy should be monitored with regard to assumption 9: there has been recent growth of anti-vaccine sentiment in the US and there could be behavioural impacts from issues with new vaccines such as Dengvaxia (a licensed dengue vaccine for which additional analyses in 2017 show that "the subset of trial participants who were inferred to be seronegative at time of first vaccination had a significantly higher risk of more severe dengue and hospitalizations from dengue compared to unvaccinated participants").

Summary of project's progress towards last year's issues and recommendations that were made.
N/A

List of Recommendations
3.1 The developing evaluation strategy should include review of all assumptions. For example using analysis of application numbers to each competition and interviews/surveys of the research community to assess assumption 2. This will also help inform future strategy.

4. External Engagement

Overall delivery confidence assessment for project's finance.

Risk Rating: Amber/Green (Medium Low)

The Vaccines Project has engaged actively with the research community through its funding competitions and has increased its engagement with wider stakeholders. The team are currently producing a proactive communications strategy to communicate the successes of the Project, particularly increasing engagement with the wider public.

Risk reviewed since last annual review: Yes ☐ No ☐ N/A ☒

4.1. Evidence of use and success of the communication strategy.

Overview of the project communication strategy and its relevance to the project aims.

For the majority of the review period communications have been focused on advertising funding competitions. The numbers below represent the number of applications for each competition (and the number which were successful in receiving funding):

- Pre-clinical Vaccine Development (Innovate UK): 33 (22)
- Clinical Vaccine Development (Innovate UK): 11 (7)
- Vaccine Manufacturing Hub (EPSRC): 3 (2)
- One Health (BBSRC): 10 (5)
- Epidemiology for Vaccinology (NIHR-CCF): 12 (5)

This demonstrates the direct impact of engagement with the academic community. Due to the ODA requirement within these projects, it is difficult for delivery partners to determine precisely how these figures compare with applications for other, non ODA competitions. However, as an example, Innovate UK expected approximately 40 applications for the Preclinical Vaccine Development competition, of which they expected 20 to be above the quality threshold. Whilst only 33 applications were received, 21 of these were above the quality threshold. The Clinical Vaccine Development competition followed a similar pattern, demonstrating that, whilst application numbers were lower than expected, a higher proportion of the applications received were of a high quality. This suggests that whilst the reach of the competitions could potentially be improved, the right people within the academic and SME community have been engaged.

To date, engagement with the press has been mostly reactive, based on when universities or projects have been engaging with the media. These press releases have raised awareness of individual projects, including one of the Vaccine Manufacturing Hubs and one of the research projects focusing on Zika. These were supported by the delivery partners, the Vaccines Project team, the GHS communications manager and the DHSC communications team, through issuing ministerial quotes, offering the opportunity to facilitate filming on location (although this was not taken up), and sharing press releases on social media and project information on our web page.

The project manages the Vaccines Project web page, for which an update is in progress as described in section 4.2. On this website there is also a contact email address through which the project team are contacted with general enquiries and invitations to events.

The UKVN working groups have produced a vaccine development schematic and a decision tool which have been published on the dedicated website manged by partners at the Medical Research Council (MRC). From the launch of the two tools in September 2017 to the end of

March 2018, 428 users have visited the site, accessing the site in 6 different languages. The UKVN working groups are continuing to develop these tools and are working on publications in academic journals by November 2018, which will further extend their reach.

The project team is currently developing a communications strategy to build on these successes and to drive a more proactive, consistent and effective approach, with the support of the GHS communications lead. This will include a plan for proactive communications to advertise the successes of the Vaccines Project, as well as a plan for how to handle reactive communications. The team is engaging with external stakeholders to develop this strategy, for example the communications lead at the Wellcome Trust, to identify opportunities for cross–collaboration and to ensure an outward facing approach is taken.

As the first step to advertise the scale of the work DHSC is funding, the project team issued a press release to publicise the funding of seven clinical stage projects to coincide with the Global Health Security Initiative meeting at the beginning of March. This was picked up by the 'Hippocratic Post' website but no major news outlets, therefore the team will work with communications colleagues to improve the likelihood of pick-up of future releases by mainstream media.

4.2. Evidence of external engagement.

Overview of project's engagement with the following:

Stakeholders

The project team have engaged with external experts from industry and academia through UKVN meetings. The Network met approximately three times per year over 2015 and 2016, before agreeing to meet annually from 2017. This has provided regular opportunities for the project team and the CSA to engage with members of the Network, who represent funders, academics and industry stakeholders. In addition to these meetings, the project team has also engaged with members of the Network through working groups.

The project team regularly meets with the MRC, the Wellcome Trust, CEPI and colleagues in BEIS who are leading other research-focused ODA programmes. This is to ensure the team maintain an understanding of activity in the field, share learning where appropriate and identify opportunities for collaboration.

Industry

The UKVN and working groups have involved approximately 15 contributors from industry. Three Small Business Research Initiative (SBRI) competitions have been run through Innovate UK, which has led to 19 SME-led projects receiving funding through the Vaccines Project.

Public Audience

The UKVN webpage on gov.uk has been updated to reflect the competitions which have been held over the past 18 months. This request has been issued and is in the process of being actioned.

The project team has also engaged with the public using our DHSC GHS Twitter channel. This has included 5 direct tweets reaching 1342 users with an engagement rate (people clicking the link / retweeting / following us, etc.) of 1.93% people (the industry standard for engagement is 1%).

The team-led press release and support of the two press releases issued by partners, as described in 4.1, has also contributed to engagement with the public with the stories being picked up by mainstream media channels including the BBC.

Research industry

The project team has engaged with the research industry through its delivery partners via the seven competitions held. The team will continue to build on this engagement going forwards through the communications strategy.

Summary of project's progress towards last year's issues and recommendations that were made.
N/A

List of Recommendations
4.1 Finalise and implement project communications strategy to improve proactive communications and extend reach, including building on relationships with stakeholders to collaborate where beneficial.
4.2 Continue to support UKVN academics to publish the outputs of working groups 1, 2 and 3 in academic journals to raise awareness of the website tools within academic audiences.
4.3 Linked to recommendation 3.1, develop the evaluation process so that it considers the reach of the competitions to understand how to improve this for future competitions.

5. Lessons Learned

Evidence of learning and continuous improvement during the projects implementation and how lessons will be shared more widely.

In summary, Oct 2016 to Mar 2018 has been a positive 18 months for the Vaccines Project from a standing start. Successes include the delivery of all 7 planned competitions and the associated establishment of a diverse portfolio of research projects that meet the needs identified by the UKVN. This is an especially noteworthy achievement considering the limited team resources for 6 months of this period.

Since October 2017, the fully-staffed project team have built on this success by optimising the project management processes and further strengthening relationships with delivery partners. There is more work to be done including around stakeholder engagement and wider communication of the project, and these challenges will be the focus of the team for the coming year.

Lessons and Improvements for the future:

1. Delivery partner engagement

A key piece of learning for the team has been the importance of building strong relationships and maintaining regular communication with delivery partners (see section 1.5). Since fully staffed, the team have taken a proactive approach in applying this learning, including establishing the Project Delivery Board and instigating regular meetings and/or communication with partners. Building on the experience of this project, if additional delivery partner relationships are needed in the future (for this or similar programmes) providing early clarity on what each partner should expect from the relationship will be essential.

2. Supporting the research community to understand the unique financial reporting requirements of ODA funding

Since the beginning of the Vaccines Project obtaining accurate forecasts from the projects we fund has been challenging. Conversations with delivery partners suggest that this is likely because many awardees, while increasingly aware of ODA compliance requirements, require additional support regarding the additional financial reporting requirements that come with ODA funding, requirements which are very different from the financial approach of traditional academic research grants.

To support the research community in ODA financial forecasting, and to overcome these challenges in future, project teams will work closely with delivery partners to raise awareness of these differences at the point of application (so applicants are aware of the extra financial scrutiny they will face if successful) and increase the scrutiny and challenge placed on work plans and associated forecasts at the point of award.

3. Vaccine manufacturing costs and delays

A number of our NETSCC-managed clinical projects have requested additional financial assistance and increased time to help cover complications encountered with the manufacture of their vaccines. These complications have been due to a number of issues, including unusually large exchange rate fluctuations between GBP and the euro and technical complications (such as stability and yield of the vaccine in the work prior to manufacture) and have been further compounded by the relatively limited GMP manufacturing facilities available to the researchers. Overall, the result has been increases in the cost and length of 3 of the 6 projects managed by NETSCC.

Similar challenges with progressing from preclinical to clinical development of vaccine candidates has also been experienced by 2 of the 5 Innovate UK funded clinical projects from the 2016 competition, with time extensions granted to these projects. Furthermore, the Innovate UK SBRI process, through which these projects are funded, does not allow for financial extensions (without a competitive process) therefore one of these projects has been forced to reduce the scope of their work, now no longer completing a human clinical trial, due to the technical difficulties they have encountered.

Although the complicated nature of the research we are funding means that such risks can never be completely removed, the project team will continue to work closely with delivery partners and the UKVN to consider how best to deal with the likelihood of such manufacturing and technical issues within clinical projects. This will support the development of mitigation options and/or the design of future clinical research competitions by the vaccines team, the wider GHS teams or other ODA programmes where similar issues could occur.

4. Other delays to projects

A number of projects have also been delayed by 1-4 months due to issues in recruiting the necessary technical staff to complete the work. In future the design of competitions will address the likelihood of this issue. For example, the time between the award of funding and the required start date of project spending should be increased as this proved unrealistic for some of our competitions. This learning is now incorporated into our financial scenario planning and has also been shared with the GAMRIF team as they initiate a research competition with BBSRC.

Finally a number of projects were delayed because they have been unable to obtain the necessary licenses for their animal or human work within the time they allowed for this in their application. Such factors should be carefully considered for future competitions, with potential to build in contingencies or to challenge projects on how realistic their time frames are at the award stage.

6. Project Delivery and Recommendations

Please insert overall delivery confidence RAG ratings:

1	Project Management	Amber/Green
2	Finance	Amber/Green
3	Theory of Change	Not Applicable
4	External Engagement	Amber/Green
5	Overall delivery confidence rating:	Amber/Green

List of Recommendations

Section 1. Project Management

1.1 Invite feedback from delivery partners on our relationship management to identify further improvements.

1.2 Proactively increase engagement with DFID teams and the WHO R&D blueprint teams to inform project strategy and prevent duplication of work.

1.3 Produce a clear milestone delivery plan and log frame for Apr 2018-Mar 2019 to support project progression and aid delivery assessment.

Section 2. Finance

2.1 Work closely with delivery partners, and in particular the partners for whom expenditure is in the early stages, to ensure that the ODA reporting requirements are well understood.

2.2 Ensure delivery partners provide updates on project progress at agreed intervals, including actual expenditure and revised forecasts, to increase DHSC confidence in the in-year monitoring returns submitted to DFID/HMT.

2.3 Publish documents for the UK Vaccine Network on Gov.UK or an alternative accessible URL to increase the project transparency score. DFID have a list of 12 recommended documents to publish (if available), which include: Business case; Logframe; MoU/MoU amendments; Annual Review; and Evaluation report.

2.4 Encourage delivery partners to attend the DHSC Transparency workshop, which is scheduled to be hosted in early summer 2018, to ensure that they are aware of their Transparency requirements.

Section 3. Theory of Change

3.1 The developing evaluation strategy should include review of all assumptions. For example using analysis of application numbers to each competition and interviews/surveys of the research community to assess assumption 2. This will also help inform future strategy.

Section 4. External Engagement

4.1 Finalise and implement project communications strategy to improve proactive communications and extend reach, including building on relationships with stakeholders to collaborate where beneficial.

4.2 Continue to support UKVN academics to publish the outputs of working groups 1, 2 and 3 in

List of Recommendations
academic journals to raise awareness of the website tools within academic audiences. 4.3 Linked to recommendation 3.1, develop the evaluation process so that it considers the reach of the competitions to understand how to improve this for future competitions.

Annex A


THE VACCINES PROJECT
ACTIVITIES
OUTPUTS
OUTCOMES
IMPACT
Research & development
Research and clinical trials for vaccine candidates
Epidemiological research
Infrastructure & equipment
Hub for innovative vaccine manufacturing
Engagement & Policy
The UK Vaccine Network
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
Funding supports UK research in this field, ensuring inclusion of both academia and SMEs
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 competitiveness and reputation in vaccine R&D is maintained and UK is well-placed to support future Public Health Emergencies
AMR
Prevention and reduction of the likelihood of public health emergencies such as outbreaks and AMR
Rapid and effective response, building on robust preparedness