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# Evaluation of the UK Vaccine Network Project 1.0 (NIHR207661)

## **Final Report Appendix**

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## Disclaimer

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## Appendix A Portfolio approach and stakeholder consultations

#### A.1 Overview

The study team compiled a database of UKVN 1.0 projects in scope for the evaluation, containing project references, timeframe, grant value, and other information, as provided by UKVN 1.0 delivery partners: BBSRC, EPSRC, Innovate UK, NIHR CCF, and NIHR NETSCC. We noted that there was no harmonised monitoring and reporting system in place for all UKVN-funded projects, but delivery partners were tasked to implement a suitable monitoring process, often aligned with their standard reporting requirements.

The database created for the evaluation was populated with information from: (1) final project reports; (2) Researchfish; and (3) survey data.

## A.2 Final project reports

Final reports describe the project activities, outputs and outcomes for each project at project closure and these were shared with the evaluation team for analysis. These reports varied in format, structure and content for each delivery partner and, in some instances, for each competition. This provided a challenge for the evaluation team to create a consistent dataset encompassing the UKVN 1.0 portfolio.

The study team analysed each final report to capture information about the UKVN portfolio and allow integration with other structured data (i.e., Researchfish and survey) that updates and extends relevant information since project closure. The structured dataset allowed a quantitative analysis with the following objectives:

- To identify the pathogens covered in funded projects
- To assess whether the projects had achieved their objectives
- To obtain detailed information about project activities (e.g. development of vaccine candidates, platforms, models or other)
- To determine the vaccine R&D stage at the start and the end of the project, following the UKVN Vaccine Development Map<sup>1</sup>
- To obtain information about project outputs, such as publications, patents, spinouts, clinical trials, and others.

The first step in the analysis of final reports consisted of an automated text mining approach to extract text from PDFs into a structured Excel file. Using Python and regular expressions (sequence of characters to match specific text), the automated approach identified key report sections and extracted relevant data for analysis. This approach produced mixed results due to the narrative style and different formats of the reports. While structured elements, such as publication lists, were extracted more successfully, more complex elements (e.g. vaccine R&D progress) could not be extracted adequately.

The second step consisted of a manual analysis of each final report to capture information systematically. This step involved two study team members reading relevant sections of the reports and recording findings in an Excel file, according to a defined thematic framework. To ensure consistency, the team members conducted preliminary analysis of a small number of reports for each delivery partner and discussed the findings to sense check and validate the approach. The thematic framework covered:

Pathogen coverage, including both UKVN and non-UKVN priority pathogens

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<sup>1</sup> https://www.vaccinedevelopment.org.uk/index.html



- Assessment of whether the projects achieved their objectives
- If applicable, type of technology developed for those not directly involved in development of vaccine candidates (e.g. diagnostics tools)
- Mapping of high-level vaccine R&D stages (pre-clinical discovery, pre-clinical development, and clinical development) and more granular R&D steps within each stage
- Information and references to clinical trials
- Publications and engagement outputs, such as peer-reviewed articles, talks and presentations
- Patents, spinouts and other commercial data
- Partner names, for those projects missing partner information in the database.

## A.3 Researchfish data

Quantitative analysis was conducted on the latest Researchfish data available on Gateway to Research (GtR, March 2024)<sup>2</sup>. This includes data on publications, engagement activities, commercial outputs and others by individual project.

Within the UKVN portfolio, only BBSRC and EPSRC grants (n=7) report outputs and outcomes on GtR. Relevant data from these grants was extracted and used to triangulate with other data sources.

## A.4 Surveys

Two online surveys were distributed to (1) successful and (2) unsuccessful applicants to UKVN competitions. The surveys aimed to update and expand our knowledge of projects outputs, outcomes and impacts. For unsuccessful applicants, the survey aimed to obtain information on how unsuccessful applicants might have progressed their ideas since application to a UKVN competition.

## A.4.1 Survey approach

Surveys consisted of close- and open-ended questions, asking stakeholders to provide information across key topics for their projects and applications, as outlined in Table 1 below.

Table 1 Survey topics

Survey target	Survey topics	
Successful applicants	<ul> <li>Project team composition and experience</li> <li>Co-funding</li> <li>Vaccine R&amp;D progress</li> <li>Research, Commercial and Other Outputs</li> <li>Follow-on work and barriers</li> <li>Skills and capacity</li> <li>Outcomes for low- and middle-income countries</li> <li>Design and management of the funding competition</li> </ul>	

<sup>&</sup>lt;sup>2</sup> https://gtr.ukri.org/



Unsuccessful applicants	Proposal area/pathogen focus
	Further research and innovation activity
	Project results and outputs (if applicable)
	Design and management of the funding competition

The successful applicants survey link was disseminated to project leads with a request to complete a survey response per project. Since multiple linked grants for the same project leads may focus on the same research direction, for practical reasons, 'project' was defined in the survey as **one or more UKVN grants** supporting activities involving the same research focus and/or pathogen. In particular,

- Project leads awarded a grant in a Stage 1 competition and, who had subsequently received follow-on funding in a Stage 2 competition for the same pathogen were asked to provide a survey response for the two grants as one project
- Project leads awarded more than one UKVN grants for unrelated research projects were asked to provide separate survey responses for the two projects
  - Project leads with three or more projects were asked to complete survey responses for two projects only, selected by the study team to maximise pathogen coverage while reducing burden on respondents

This approach included all 61 project leads and encompassed 76 UKVN projects representing 92 UKVN grants – covering approximately 94% of the UKVN portfolio (81 projects and 99 grants). A small number of projects were excluded from survey invitations to reduce burden on project leads with three or more projects.

Project partners were also invited to complete a shorter version of the survey. The list of project partners and their contact details was not available in monitoring documents and therefore project leads were asked to invite their project partners to complete the survey, or share their details with the study team.

The unsuccessful applicants survey was disseminated via delivery partners and via direct invitations. Individuals who were both successful and unsuccessful applicants in a UKVN competition were not invited to complete the unsuccessful applicants survey.

- EPSRC and NIHR (CCF) disseminated the survey link to unsuccessful applicants on behalf of the study team (approximately 8 unsuccessful applicants)
- Unsuccessful applicants' details from Innovate UK competitions were shared with the study team who emailed them directly (n = 15)
- NIHR (NETSCC) could not identify details of unsuccessful applicants as competitions were managed by MRC/BBSRC in 2015/16
- BBSRC did not respond to the study team's request to disseminate the survey link with unsuccessful applicants

Both surveys launched on 5 December 2024 and closed on 19 January 2025. Three reminders and one notice of survey extension were sent to invitees.

Approximately 30% of project leads (n = 21) confirmed receipt of the email request to complete the survey and to disseminate the link to their project partners. Several email addresses for both successful (n = 8) and unsuccessful applicants (n = 9) were outdated. The study team attempted to find alternative contacts for these applicants but had limited success.



## A.4.2 Survey response rates

A total of 56 survey responses were received from successful applicants, including 33 from project leads (54% response rate) and 23 from project partners. We use n = 56 when reporting survey answers specific to stakeholders' experiences rather than projects, for example skills & training and design of the UKVN1.0.

The 56 survey responses covered **39 individual projects**, representing approximately 50% of the UKVN projects in scope for the survey and 48 of grants (63%), see Table 2. Analysis of project related questions are based on  $\bf n = 39$ , with some projects represented by multiple respondents. Where relevant, responses were aggregated to maintain a consistent unit of analysis.

Table 2 Survey	responses by a	deliverv na	rtner and	number ot	projects

Delivery partner	Number of projects in scope for the survey	Number of projects with a survey response	Number of grants in scope for the survey	Number of grants with a survey response
BBSRC	5	3 (60%)	5	3 (60%)
EPSRC	2	2(100%)	2	2(100%)
Innovate UK	58	25 (43%)	74	34 (46%)
NIHR (CCF)	5	4 (80%)	5	4 (80%)
NIHR (NETSCC)	6	5 (83%)	6	5 (83%)
Total	76	39 (51%)	92	48 (63%)

For unsuccessful applicants, only one response was received, and therefore it was excluded from the analysis.

#### A.4.3 Survey analysis and combination with portfolio data

Portfolio data was consolidated across the three data resources where available (i.e., final reports, Researchfish data and survey results). The survey allowed respondents to provide upto-date information since the submission of final reports or uploading information to Researchfish. The survey also gathered data on topics that are not covered in Researchfish submissions or final project reports (e.g. team experience and process-related questions).

Project outputs from each data source, such as publication lists and commercial outputs, were compiled and merged, where possible, to ensure that there is no duplication of reported data. Information from each of the sources was populated and manually cleaned in MS Excel spreadsheets, where outputs attributed to individual projects could be compared and deduplicated.

The survey included multiple open text questions to enable respondents to provide additional perspectives and details to closed questions. These survey responses were analysed in MS Excel also, where identified themes were grouped and coded to enable aggregated reporting of narrative findings.

#### A.5 Limitations

There are several limitations that affect the robustness of the findings of the portfolio analysis. First, the UKVN 1.0 is diverse in scope of its underlying projects, disciplines, and technology areas, as well as in the timelines projects were implemented. This may impede a programmatic view of the evaluation. The early-stage nature of research and innovation activities funded by



the UKVN 1.0 also means that some outcomes and impacts may not be observed at the time of the evaluation, when some projects are only recently completed.

The portfolio analysis included limitations related to data coverage and quality, and a degree of under- and overreporting may be present in final project reports, Researchfish and survey responses. Triangulation of data from these three sources helped to mitigate this issue, though some gaps likely remained, for example in fully capturing all types and volumes of outputs. The analysis of final reports was hampered by varying report structures, their qualitative nature and extensive narrative content. The study team had to interpret certain texts referring to outputs and outcomes described in final reports. Due to the technical complexity and diversity of funded projects, determination of R&D progress precisely was in some cases challenging. Lastly, most final reports were completed within a few months after project completion, meaning some reports reflect the status quo of oversix years ago. Nevertheless, data extracted from final reports describe the activities and direct outputs of each UKVN project achieved in the funding period.

Regarding survey responses, some project leads and partners were not contactable due to staff turnover, and challenges in stakeholder engagement also limited the number of responses received.

## A.6 Clinical trials analysis

The WHO International Clinical Trials Registry Platform<sup>3</sup> was searched for clinical trials of vaccines addressing the 12 priority disease areas, using the search terms "[disease] AND vaccine", for Phase I, II, III, and IV studies. Data was collected on a) the registration number of the most advanced clinical trial and trial phase, b) the name of the vaccine candidate, c) the year of first enrolment of the corresponding first in human trial, d) the type of vaccine technology, and e) the status of the trial. The data was completed and verified by conducting targeted online searches of the academic literature (e.g. recent reviews of vaccine landscapes) and grey literature (e.g. company announcements).

UKVN-funded vaccine candidates were then identified by cross-referencing the clinical trial candidate list with UKVN 1.0 project portfolio, and verifying this through final project reports, survey responses, acknowledgements in academic publications, and targeted online searches.

## A.7 Scoping interviews

In the inception phase of the evaluation, we conducted 10 scoping interviews with 13 individuals previously or currently involved in UKVN Project 1.0. Scoping interviews were conducted between 21 June and 6 August 2024. The interviewees are listed in Table 3.

Table 3 List of stakeholders interviewed

Interview ref	Name	Organisation	Current or previous role in UKVN Project 1.0
1	Madeleine Clark	BBSRC	
2	Laura Totterdell	EPSRC	Delivery partner

<sup>&</sup>lt;sup>3</sup> <a href="https://trialsearch.who.int/">https://trialsearch.who.int/</a>



Interview ref	Name	Organisation	Current or previous role in UKVN Project 1.0
	Stephanie Williams		
	Richard Bailey		
3	Phil Packer	Innovate UK	
4	Martin Broadstock	King's College London	
5	Lisa Marsh	NIHR NETSCC	
6	Mike Rogers	NIHR-CCF	
7	Danielle Edge		
7	Frances Butcher	DUI00	
8	Helen Tomkys	DHSC	UKVN Project Team
9	Jennifer Stuart		
10	Alex Mclaughlin	OLS	

Source: Evaluation team, 2024.

The interview questions covered the following aspects:

- The UKVN Project 1.0 strategic aims and the wider context
- The UKVN Project 1.0 design, governance and delivery model
- The key stakeholders and data available for the evaluation
- To the expected (or achieved) outputs, outcomes and impacts
- The role of the evaluation and how findings will be used

Data from scoping interviews were combined with preliminary analysis of documents to build on our knowledge about the UKVN 1.0's context, design and delivery model.

## A.8 Interviews with project leads

A total of 17 project leads were interviewed for the 18 case studies developed for the evaluation, as shown in Table 4.

Table 4 Project lead interviewees for case studies

rable 1 Troject lead internet accitet case steales		
Interviewee	Organisation	
Dr Neil Almond	National Institute for Biological Standards and Control	
Professor Imre Berger	Imperial College London	
Professor John Edmunds	London School of Hygiene & Tropical Medicine	
Professor Neil French	University of Liverpool	



Interviewee	Organisation
Professor Sarah Gilbert	University of Oxford (MRC Centre for Human Immunology)
Professor Jonathan Heeney	University of Cambridge
Professor Pontiano Kaleebu	University of Oxford (MRC Uganda Virus Research Institute)
Professor Teresa Lambe	University of Oxford
Professor Shelley Lees	London School of Hygiene & Tropical Medicine
Dr Olga Pleguezuelos	Imutex Limited
Professor Sir Andrew Pollard	University of Oxford (Oxford Vaccine Group)
Professor Robert Possee	Oxford Expression Technologies
Associate Professor Chrissy h Roberts	London School of Hygiene & Tropical Medicine
Professor Matthew Snape	University of Oxford
Richard Vellacott	Biologic Technologies Limited
Professor George Warimwe	The Pirbright Institute
Professor Brendan Wren	University College London

## A.9 Interviews with wider stakeholders

A programme of interviews was conducted with individuals not directly involved in the UKVN 1.0 but with substantial experience in vaccine R&D across academia, industry and funding bodies. The objectives were to gather external perspectives on:

- The substantial and added value of the UKVN's within the broader R&D ecosystem
- The extent to which the UKVN has supported resource allocation towards priority areas and addressed barriers in the vaccine R&D landscape
- The UKVN 1.0's potential impact in beneficiary countries

The evaluation team developed a long list of potential interviewees, including experts from LMICs, global research funders, policymakers and private sector. The list was refined in consultation with DHSC, and 33 invitations were sent, followed by reminders. A total of 19 interviewees were conducted.

Table 5 Number of wider stakeholders interview invitations and interviews conducted

Stakeholder group	Number o	of invitations s Is from	Number of individuals interviewed			
Crancillo group	LMICs	HICs	Total	LMICs	HICs	Total
Academia / Research Institute	2	3	5	1	2	3
Global health initiative	2	2	4	1	1	2
Global health policy maker and implementer	2	2	4		2	2



National Health Institution / Agency	6		6			
Research Funders / Global health initiative		8	8		7	7
Vaccine R&D companies (non-beneficiary of UKVN funding)	2	3	5	1	3	4
Vaccine R&D Infrastructure		1	1		1	1
Total	14	19	33	3	16	19

In total, individuals from 16 organisations were interviewed:

- Africa Health Research Institute
- Afrigen Biologics and Vaccines
- BioVacc Consulting Ltd
- Centauri Therapeutics
- CEPI
- FDA Ghana
- International Pandemic Preparedness Secretariat (IPPS)
- Jenner Institute
- Cell & Gene Therapy Catapult
- National Institute of Health (NIH)
- PATH
- The Vaccine Group
- UKRI/MRC
- Various scientific advisory boards
- WHO
- WHO Regional Office for Africa

All interviews were conducted online and recorded for analysis. Interviews lasted 30 to 60min. Analysis was conducted using a coding framework in Excel based on the questions topics and emerging themes.



## Appendix B Overview of the UKVN portfolio

## B.1 Applications to UKVN funding

At least 169 applications for funding were submitted across all competitions (see Table 6). This figure is likely an underestimate, as the total could not be confirmed across all delivery partners. A total of 99 applications were successful.

Table 6 Number of applications to UKVN competitions

Delivery partner	Research competition	Total number of applications	Number of successful applications	Number of unsuccessful applications
BBSRC	'One Health' competition	10	5	5
NIHR (NETSCC)	Development of vaccine candidates - UKVN NETSCC Intramural Proposals. Projects supported through MRC/BBSRC Centres of Excellence	Not identified	6	Not identified
NIHR (CCF)	Epidemiology for Vaccinology' competition	12 applications at outline stage, 8 at full application stage	5	7
EPSRC	Future Manufacturing Research Hub Competition	3	2	1
	Vaccine Development Competition (£10m): Stage 1, Stream 1 – smaller awards to support proposals that are at an earlier stage of development	33	15	18
	Vaccine Development Competition: Stage 2, Stream 1 – further, larger awards for projects successful at Stage 1, Stream 1 and ready for more advanced development	10 to 15	4	6 to 11
Innovate UK	Vaccine Development Competition (£10m): Stage 1, Stream 2 – larger awards for projects that are at a more advanced stage of development and are likely to go into Phase I first-in-human trials within the next 12 months	11	5	6
	Development of candidate vaccines and vaccine platform technologies at the preclinical stage (£25m)	34	22	12
	Development of candidate vaccines and vaccine platform technologies at the preclinical stage (£25m) - Stage 2	13	7	6
	Development of candidate vaccines and vaccine platform technologies at the clinical stage (£35m)		7	4
	Vaccines for epidemic diseases (Small Business Research Initiative, SBRI)	Not identified	21	Not identified



Source: Data shared by delivery partners. Note: Uncertainty remains about the number of applications received for NIHR (NETSCC) and last Innovate UK SBRI competition Number of applications was calculated by (i) information from delivery partners via email (NIHR CCF); and (ii) list of unsuccessful applicants (Innovate UK).

## B.2 Overview of UKVN projects

The UKVN 1.0 portfolio consisted of 99 project grants which ran from 2016 to 2023 (with one exception of a project running through 2024). Innovate UK awarded the vast majority of grants (n = 81), representing approximately 62% of the total grant value for the UKVN 1.0. Importantly, the grant values identified may not fully account for all cost extensions provided through the UKVN 1.0. For this reason, the total grant value for the UKVN 1.0 identified in the current analysis was £117.4m, much lower than the £134m outlined in the business case addenda. Table 7 provides an overview of the UKVN Project 1.0 portfolio.

Table 7 Overview of UKVN Project 1.0 portfolio

Delivery partner	Research competition	Date range of projects	Average project duration (years)	No. of grants	Approx. total grant value (% of total)
BBSRC	'One Health' competition	2018 to 2021	3.9	5	£5.4m (5%)
EPSRC	Future Manufacturing Research Hub competition	2016 to 2021	5.5	2	£22.6m (19%)
Innovate UK  Vaccine Development Competition (£10m): Stage 1, Stream 1 – smaller awards to support proposals that are at an earlier stage of development		2017 to 2017	1	15	£6.2m (5%)
	Vaccine Development Competition (£10m): Stage 1, Stream 2 – larger awards for projects that are at a more advanced stage of development and are likely to go into Phase I first-in-human trials within the next 12 months	2016 to 2019	3	5	£4.6m (4%)
	Vaccine Development Competition: Stage 2, Stream 1 – further, larger awards for projects successful at Stage 1, Stream 1 and ready for more advanced development	2018 to 2022	3.5	4*	£8.6m (7%)
	Development of candidate vaccines and vaccine platform technologies at the preclinical stage (£25m)	2017 to 2018	1	22	£9.6m (8%)
Development of candidate vaccines and va platform technologies at the preclinical stage - Stage 2		2018 to 2022	3.8	7*	£14.1m (12%)
	Development of candidate vaccines and vaccine platform technologies at the clinical stage (£35m)	2017 to 2022	4.4	7	£20.7m (18%)
	Vaccines for epidemic diseases (Small Business Research Initiative)	2022 to 2023	1.2	21*	£9.3 (8%)
NIHR (CCF)	Epidemiology for Vaccinology competition	2018 to 2022	3	5	£4.2 (4%)

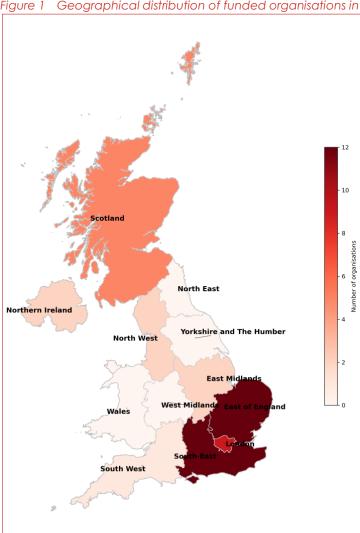


Total	·otal					
NIHR (NETSCC)	Development of vaccine candidates - UKVN NETSCC Intramural Proposals. Projects supported through MRC/BBSRC Centres of Excellence	2016 to 2021	4.3	6	£12m (10%)	

Source: Portfolio analysis, 2024.

A total of 48 unique organisations were associated with project leads, of which 24 academic organisations (University / Research Institute), 22 companies and 2 UK executive agencies (Medicines and Healthcare products Regulatory Agency and UK Health Security Agency). All organisations were based in the UK, with the exception of Themis Bioscience GmbH (Austria), MRC Uganda Virus Research Institute (Uganda) and Vaxinano (France).

Figure 1 Geographical distribution of funded organisations in the UK



As shown in Figure 1, most UK organisations were based in the South East of England, East of England and London.

Academic organisations were awarded approximately £83.8m across all competitions (71% of all funding), companies £28m (24%) and UK executive agencies £5.6m (5%).

A total of 20 organisations were awarded more than one grant. A relatively small number organisations led over 50% of all 99 grants (n = 11 organisations)representing nearly 60% of UKVN budget (approximately £66.7m). The 11 organisations consist of mostly academic and research institutions (e.g. Jenner Institute, Imperial College, the Pirbright Institute) but also the UK Health Security Agency and companies such as Excivion Ltd, Iosbio Ltd (previously Stabilitech Limited) and Oxford Expression Technologies.

#### B.3 UKVN project partner

## organisations

UKVN project partner organisations were mapped to identify the number, type of and geographical location of organisations involved in project activities.



Data on partners was gathered through multiple sources. Project documentation shared with the study team included a Delivery Chain Map outlining partner organisations for 57 UKVN grant references as of 2021. This source was complemented with analysis of final project reports.

The Delivery Chain Map file described 'partners' in a number of different ways, including coapplicants, sub-contractors or contractors, project managers and collaborators. We therefore adopted a broad definition of partner organisations, as any organisation involved in the project delivery, as reported in the Delivery Chain Map and/or mentioned in final project report. This approach offers insights into the number of organisations participating in UKVN projects; however, it provides limited information regarding the specific roles partner organisations played in the various projects.

A total of 186 unique partner organisations were identified for 94 out of the total 99 UKVN grants (95%).

- Each UKVN grant had on average 3 to 4 partner organisations
- Companies represented nearly 40% of partner organisations (n = 73), including biotech companies, consultancy and law firms
- Partner organisations also included universities (n = 51, 27%) and research institutes (n = 39, 21%)
- The remaining partner organisations included hospitals, manufacturing facilities, government agencies, NGOs and others
- At least 44 partner organisations were identified as project leads in other UKVN projects, indicating close collaboration across UKVN portfolio
- The most frequently occurring partner organisations included UK Health Security Agency, pharmaceutical company Covance, UK's Defence Security and Technology Laboratory and University of Oxford (including its Clinical Biomanufacturing Facility)

Approximately three-quarters of organisations were based in high-income countries (n = 139, 74%), of which most are based in the UK (n = 85), followed by the USA (n = 19) and Germany (n = 8). The remaining 44 organisations with associated countries identified were based in low-and middle-income countries, mostly based in the African continent (n = 19), including Uganda (n = 5), Nigeria (n = 3) and Kenya (n = 2); Asia (n = 16), including India (n = 8), and North America (Mexico, n = 7) were also represented. Figure 2 provides a map of partner organisations' location.



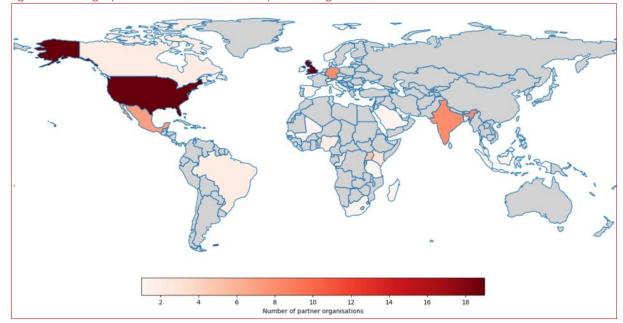


Figure 2 Geographical distribution of UKVN partner organisations

Source: Evaluation team. Partners based in the United Kingdom (n = 85) are not fully represented in the colour scale to improve visibility of other countries.

## B.4 Co-funding of UKVN 1.0 projects

Additional funding obtained for UKVN projects from other sources (at the time of implementation of UKVN projects, not follow-on funding) may signal financial leverage or value for money for the UKVN 1.0. Few project final reports or survey responses provided evidence of co-funding. Four survey responses indicated co-funding was obtained for their UKVN projects. The funding sources mentioned were the Coalition for Epidemic Preparedness Innovations (CEPI), Innovate UK and NIHR Oxford Biomedical Research Centre.



## Appendix C UKVN research and innovation outputs

## C.1 Research and knowledge dissemination outputs

The UKVN Theory of Change foresees high-quality research (outputs) and a UK R&D community that is ready and able to support public health emergencies (outcomes). While the UKVN1.0 primarily targets technological development linked to vaccine candidates, the evaluation framework set out to identify publication and knowledge dissemination outputs as a measure of tangible evidence.

As noted in the portfolio approach, we used data from final reports and Researchfish, complemented by up-to-date information from project leads and partners via survey. The analysis identified research and knowledge dissemination outputs for approximately 40% of all UKVN grants (n = 40). Before presenting the analysis, we provide methodological notes which suggest that outputs reported in the evaluation may not provide a complete view of scientific production and knowledge dissemination delivered by the UKVN 1.0:

## Data completion varies across sources in relation to coverage of UKVN grants

Projects funded by EPSRC and BBSRC were required to report Researchfish data, whereas those funded by Innovate UK and NIHR were not. Additionally, responses to the survey varied across competitions and delivery partners. As a result, data availability varied substantially across grants.

## A substantial number of projects did not aim to produce research or knowledge dissemination outputs

The majority of grants in the UKVN portfolio were from Innovate UK (81 out of the total 99 grants), which primarily funded shorter projects (1-2 years) focused on technological development. Consequently, these projects were not expected to produce publications or other knowledge dissemination outputs, particularly within the project implementation timeframe. Nevertheless, about a quarter of Innovate UK grants (n = 22 out of a total of 81) produced such outputs.

To ensure accuracy, the study team de-duplicated outputs using MS Excel and manual review of output titles, dates and related metadata. All outputs were cross-checked from the three separate data sources (i.e., final project reports, Researchfish and survey responses). Below, we provide the total number of outputs identified per output type and those from the separate data sources (Table 8).

Table 8 Number of research and knowledge dissemination outputs identified by data source

Type of output	Total outputs identified	Number of outputs identified only from final project reports	Number of outputs identified only from Researchfish	Number of outputs identified only from Survey	Number of outputs identified from two or more sources triangulated
Publication	457	222 (49%)	107 (23%)	51 (11%)	77 (17%)
Knowledge dissemination	349	119 (34%)	193 (55%)	33 (9%)	4 (1%)
Other research outputs	22	n/a	17 (77%)	5 (23%)	n/a
Total	828	341 (41%)	317 (38%)	89 (11%)	81 (10%)

18



Source: Final project reports, survey responses and Researchfish data.

A total of 457 publications, 349 knowledge dissemination activities and 22 other research outputs were identified. Peer reviewed journal articles was the most common publication output (n = 382).

Table 9 Number of publications and other research outputs by sub-type and delivery partner

Type of output	Sub-type of output	BBSRC	EPSRC	Innovate UK	NIHR (CCF)	NIHR (NETSCC)	Total
	Peer-reviewed journal articles	46	187	30	104	15	382
	Conference Paper	2	23	2	9	3	39
Publication	Preprint	5	3		24		32
	Working Paper				3		3
	Book Chapter		1				1
	Research Materials	5	7				12
Other research outputs	Software		1		5		6
	Database & Models	2	2				4
Total		60	224	32	145	18	479

Source: Final project reports, survey responses and Researchfish data

The majority of knowledge dissemination outputs were scientific talks or presentations (127) but also online publications (79) and workshops (64).

Table 10 Number of knowledge dissemination outputs by sub-type and delivery partner

Sub-type of output	BBSRC	EPSRC	Innovate UK	NIHR (CCF)	NIHR (NETSCC)	Total
Talk or presentation	21	41	44	2	19	127
Magazine, Newsletter, or Online Publication	4	59	10	3	3	79
Participation in an activity, workshop or similar	10	52	1	1		64
Press release, press conference or response to a media enquiry/interview	3	33				36
Engagement focused website, blog or social media channel	5	9		6		20
A broadcast e.g. TV/radio/film/podcast (other than news/press)	1	12				13
A formal working group, expert panel or dialogue		10				10



Sub-type of output	BBSRC	EPSRC	Innovate UK	NIHR (CCF)	NIHR (NETSCC)	Total
Total	44	216	55	12	22	349

Source: Final project reports, Researchfish and survey responses.

Several workshops conducted by UKVN project teams focused on sharing knowledge with LMIC organisations. For example, researchers from the UKVN funded EPSRC manufacturing hubs conducted workshops in India, Vietnam and online:

- Workshop on 'Optimization of vaccines manufacturing, containers and testing for global supply', conducted in India in 2018<sup>4</sup>
- Workshop on 'Quality by design and supply chain management training for vaccine manufacturers', conducted in Vietnam in 2017
- Joint Webinar with IAVI on RNA vaccine technologies and applies, conducted online in 2021

These examples highlight how the UKVN has support knowledge sharing with vaccine manufacturers in LMICs. Data from one of the EPSRC hubs suggests that knowledge dissemination activities and training sessions reach over 700 individuals in the funding period (2018-2023). The total number of individuals who have benefitted across the entire UKVN 1.0 is likely substantially higher.

## C.2 Bibliometric analysis of UKVN peer-reviewed journal articles

Understanding the characteristics and impact of research outputs is critical to evaluating what constitutes 'high-quality research' and for assessing how well the UK R&D community is positioned to respond to public health emergencies. Bibliometric analysis provides a structured approach to quantify research productivity and visibility. In the context of LMICs, bibliometric analysis can also offer insights into the accessibility of research through open access publishing models and authorship data.

To explore the reach and influence of publications emerging from UK-funded projects, we conducted a targeted bibliometric analysis. This analysis focused on key metrics, including publication volume across pre-, during- and post COVID-19 pandemic periods, open access availability, patterns of authorship and citation impact.

We used Open Alex, an open-source platform that provides metadata on scientific publications. Publications identified through our portfolio analysis were matched to OpenAlex records using Digital Object Identifiers (DOIs) accessed via the OpenAlex API. Python scripts were developed to extract and analyse data for each metric The results are presented below, with additional methodological notes provided for each metric.

Out of 382 peer review journal articles / reviews from the UKVN portfolio, 349 were matched to OpenAlex records (92%). We reported all bibliometrics based on these 349 identified publications.

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<sup>4</sup> https://dcvmn.org/wp-content/uploads/2018/05/workshop\_final\_agenda\_hyderabad.pdf



## C.2.1.1 Overview of publications

From the 349 publications, 123 (35%) were associated with COVID-19 research, based on semiautomated review of publication titles and abstracts (see Figure 3). While these publications involved UKVN funding - most likely through support for researcher time - their outcomes cannot be solely attributed to the UKVN. A substantial share of COVID-19 research received co-funding from other programmes and was conducted through multi-country collaborations, some of which resulted in highly cited publications. These publications represent an unanticipated but substantial contribution of the UKVN to research beyond its core focus on the 12 priority pathogens. To avoid skewing the bibliometric analysis, publications related to COVID-19 research are presented separately in certain sections.

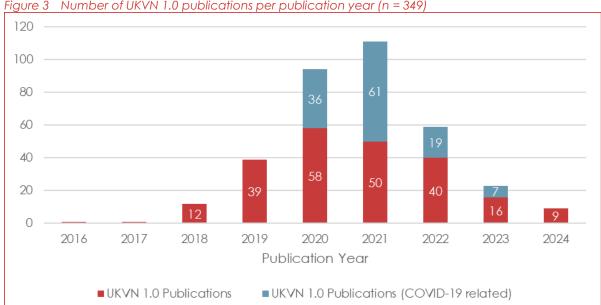


Figure 3 Number of UKVN 1.0 publications per publication year (n = 349)

Source: UKVN evaluation.

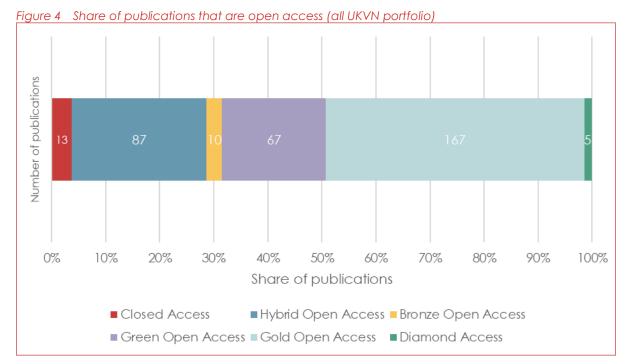
## C.2.1.2 Share of open access publications

Open Access (OA) publishing is critically important for LMICs, as it removes financial barriers to accessing scientific knowledge. Several OA models exist, each offering varying levels of accessibility:

- Diamond Open Access: articles are permanently free to read, with no restrictions.
- Gold Open Access: similar to Diamond, but often involves publication fees for authors
- Green Open Access: free versions are available, typically via repositories, but may not be the final published format
- Bronze Open Access: articles are free to read, but access may be temporary
- Hybrid Open Access: a mix of freely available and paywalled articles within the same journal, but in the case of the UKVN publications, all are freely available.

Figure 4 illustrates the share of UKVN publications that are OA. Notably, 96% of these publications fall under some form of OA model. The vast majority (over 93%) are publications permanently free to read (Diamond, Gold, Green and Hybrid), with only 3% of publications Bronze OA (temporary access) and 4% Closed (paywalled).





Source: OpenALEX and evaluation team.

## C.2.1.3 Share of author affiliated organisation types for publications over all years

From the 349 identified publications, there were 408 unique organisations involved as coauthors. To measure how each organisation contributed, we used fractional counting. Fractional counting assigns a share of contribution to each organisation based on the number of co-authoring institutions listed in a publication. For example, if a publication has authors from two organisations, each organisation is given a value of '0.5'. Table 11 provides an overview of the types of organisations over all years.

Table 11 Share of author affiliated organisation types for publications over all years

Type of organisations	Number of unique organisations (% of total)	Fractional count of authorship (% of total)
Academic/Research Institution	213 (52%)	248.3 (80%)
Healthcare	49 (12%)	13.2 (4%)
Government	44 (11%)	17.1 (6%)
Company	37 (9%)	10.5 (3%)
Research facility	35 (9%)	10.6 (3%)
Non-profit	30 (7%)	10.1 (3%)

Source: OpenALEX

When aggregated, fractional count of authorship reveals that four organisations account for nearly 40% of the total authorship contribution:

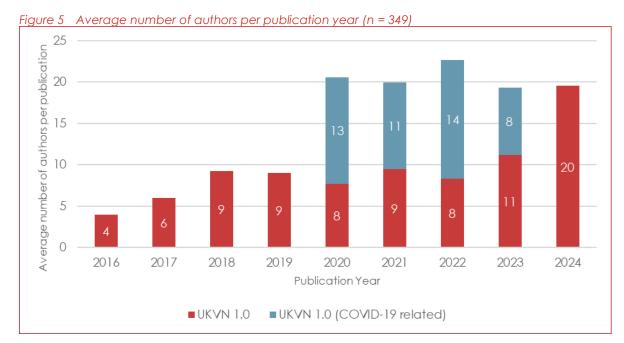
Imperial College London (11%)



- London School of Hygiene & Tropical Medicine (10%)
- University of Oxford (10%)
- University College London (7%)

## C.2.1.4 Average number of authors per publication year

Figure 5 illustrates the average number of authors per publication by year. Assuming that a high number of authors indicates greater collaboration, UKVN 1.0 publications appear highly collaborative, with an overall average of nine authors per publication across all years.



Source: OpenALEX and evaluation team.

## C.2.1.5 Share of publications with LMIC co-authorship, over all years

From the 349 publications, 76 publications had at least one author from a LMIC (approximately 22%). Most of these publications were UKVN 1.0 (n = 58) but also UKVN 1.0 (COVID-19 related) (n = 18). Co-authorship analysis identified 243 researchers from 37 LMICs across the 76 publications. The African Region accounted for the largest proportion of authors (n = 129) and countries represented (n = 15). At least one author from each WHO Region was included.

## C.2.1.6 Total citations per publication year

Figure 6 and Figure 7 illustrate the total citations per publication year, for UKVN 1.0 publications and UKVN 1.0 (COVID-19 related) publications, respectively. The total citations provide an indication of research impact over time, reflecting referencing by others in the research community.



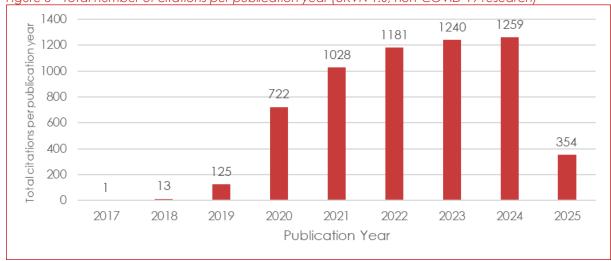


Figure 6 Total number of citations per publication year (UKVN 1.0, non-COVID-19 research)

Source: OpenALEX and evaluation team.

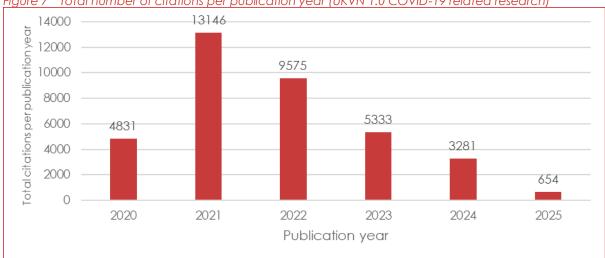


Figure 7 Total number of citations per publication year (UKVN 1.0 COVID-19 related research)

Source: OpenALEX and evaluation team.

## C.2.1.7 Average annualised citations

Annualised citations account for the age of each publication, providing a rate-based measure of research impact that enables comparison across publication years. Average annualised citations help to summarise citation performance across the UKVN portfolio.





Figure 8 Averaged annualised citations

Source: OpenALEX and evaluation team.

## C.2.1.8 Field-weighted citation impact

Field-weighted citation impact (FWCI) indicates how a publication's citation performance compares to the global average in its field, where a score of 1 represents the world average. Table 7Table 12presents the share of UKVN 1.0 publications across five FWCI categories.

Table 12 Overview of FWCI distribution of UKVN publications

FWCI categories	Share of UKVN 1.0 publications (n = 215)	Share of UKVN 1.0 Publications (COVID- 19 related) (n = 104)
1 or below	39.2%	14.0%
Between 1 and 2	21.7%	7.5%
Between 2 and 5	0.9%	33.6%
Between 5 and 10	30.7%	29.0%
Over 10	7.5%	15.9%

Source: OpenAlex. 30 publications with FWCI field missing were removed.

Over 60% of non-COVID-19 publications in the portfolio were cited more than the global average for their field. This figure rises to 86% for COVID-19 related publications. Overall, analysis of FWCI suggest that UKVN funded publications perform strongly in terms of visibility and impact relative to other publications in their field.

## C.3 Innovation outputs

Innovation outputs, such as intellectual property (IP), emerging from the UKVN1.0also constitute a proxy for success in advancing vaccine development. Information on innovation outputs were compiled from multiple sources of the portfolio analysis (as previously described). Commercial outputs, such as patents, were de-duplicated to avoid double counting. In some



instances, patent references or patent jurisdictions were not available in the data, and efforts to identify the patent through additional search were unsuccessful. These patents have been marked as 'unknown jurisdiction' in Table 13.

- Patent applications submitted: A total of 21 patents were submitted (not yet granted) by 13 UKVN projects.
- **Patents granted:** A total of 15 patents were reported by eight UKVN-funded projects, as presented in the table below.

Table 13 Patents granted through projects funded by UKVN 1.0

Source	UKVN project reference	Delivery partner	Competition area	Lead organisation type	Patent reference number (if available)	Jurisdiction (if available)
Final report	EP/R013756/1	EPSRC	Vaccine Manufacturing	University	US11179454	US
Final report	EP/R013756/1	EPSRC	Vaccine Manufacturing	University	US11278610	US
ResearchFish	EP/R013756/1	EPSRC	Vaccine Manufacturing	University	US2016051727	US
Survey	971521	Innovate UK	Preclinical stage	Government	Unknown	Unknown
Final report	972217	Innovate UK	Preclinical discovery	Company	CN112437696B	CN
Survey	972217	Innovate UK	Preclinical discovery	Company	(IIC123190) 102939371	CN
Survey	972217	Innovate UK	Preclinical discovery	Company	(IHC131091) HK1182128	Hong Kong
Survey	972217	Innovate UK	Preclinical discovery	Company	6422406	Japan
Survey	972217	Innovate UK	Preclinical discovery	Company	6507199	Japan
Survey	972217	Innovate UK	Preclinical discovery	Company	2585581	EPO
Survey	972217	Innovate UK	Preclinical discovery	Company	0064USPC	US
Survey	972223	Innovate UK	Preclinical discovery	Government	Unknown	Unknown
Final report	10025959	Innovate UK	Preclinical and clinical stages	Company	Unknown	Unknown
Final report	971558	Innovate UK	Preclinical and clinical development	University	Unknown	Unknown
Survey	16/107/05	NIHR	Clinical stage	University	WIPO 2018020271A1	WIPO

Source: Final reports, surveys, Researchfish data.



Survey respondents also noted other types of commercial outputs generated, such as the development of knowhow (two projects) and licencing agreements (three projects). However, two thirds of projects for which we received survey responses (66%, 26 out of 39 projects) stated that no commercial output could be attributed the project concerned.

- **Spin-out companies formed**: A total of four spin-out companies were identified as being formed with support from funding provided by the UKVN 1.0:
  - DIOSynVax Ltd (attributed to grant 971511 Innovate UK, final report)
  - ReNewVax Limited (attributed to grant 971554 Innovate UK, final report)
  - The Vaccine Group Limited (attributed to grant 972220 Innovate UK, final report)
  - ArkVax Limited (attributed to grant EP/R013756/1 EPSRC, survey response)



# Appendix D UKVN projects implementation and follow-on funding

## D.1 Project team and experience

The evaluation set out to explore the size and the experience of project teams at various participating organisations working on UKVN projects. The size of teams provides a measure of capacity building to contribute to a vaccines R&D community that is ready and able to respond to future public health emergencies. For this to happen, researchers need to have the specialist skills and to be able to collaborate across organisations and disciplines.

Survey answers provide an estimate of project team sizes and whether project leads and partners gained new skills through training and collaborations in UKVN projects. Due to partial response rates, the figures presented here are an underestimate of the total project team characteristics and experiences.

## D.1.1 Project team characteristics

Project team members included research students, postdocs and other staff members (e.g. permanent researchers, technicians). Survey responses from the 39 projects indicated that at least 764 project team members were involved across their projects. According to survey data, approximately half of these projects (n = 19) included teams of less than 10 individuals, a third had teams of 10-19 (n = 13), and the remaining projects had teams of 20 or more (n = 7). Project leads were asked to provide the number of project team members located in high-income countries (HICs) and in low- and middle-income countries (LMICs). We received information for a total of 39 projects. A total of 202 project team members located in LMICs were identified.

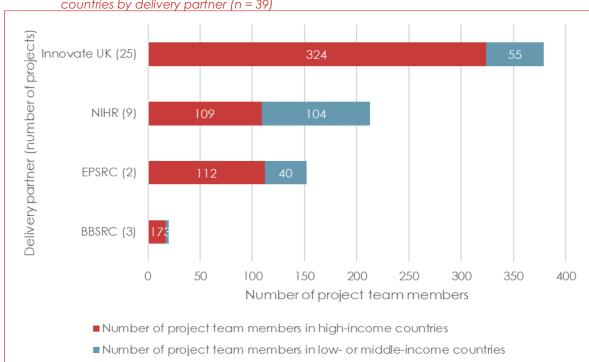


Figure 9 Number of project team members from high-income countries and low- and middle-income countries by delivery partner (n = 39)

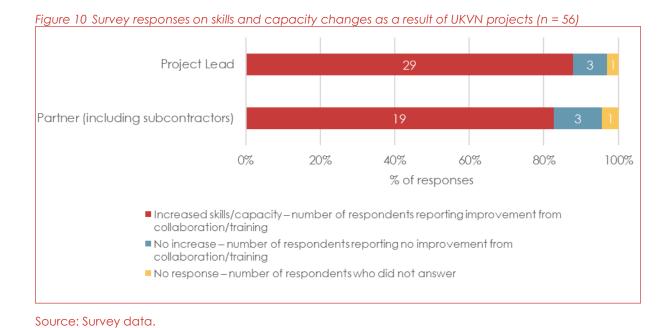
Source: Survey data.



Survey respondents were also asked whether the UKVN support new collaboration across organisations. For the 39 projects, respondents from 26 (66%) indicated that the UKVN funding generated new collaborations with some or all organisations involved.

## D.1.2 Skills and capacity development

Survey respondents were asked whether their own skills and capacity, as well as those of their colleagues, had improved as a result of collaboration with or training provided by project partners. As shown in Figure 10, over 85% of the 56 individual responses indicate their skills and capacity were increased.



Respondents were asked to specify the type of training activities undertaken. The most commonly cited activities involved scientific training and technical skill development. These consisted of training in disciplines such as biochemistry, bioinformatics, genomics, immunology, and molecular diagnostics.

Training in vaccine R&D activities was also commonly cited. Respondents reported receiving training in various aspects of vaccine development, including different vaccine platforms, the use of animal models, biosafety and containment practices, vaccine manufacturing and scale-up (e.g., bioprocessing and quality control), regulatory frameworks, and field trials.

## Has the UKVN-funded project contributed to building a stronger R&D community that is ready and able to support future public health emergencies?

When asked about the UKVN's contribution to strengthening the R&D community, survey respondents were overwhelmingly positive. Many highlighted the UKVN's substantial role in advancing vaccine R&D for the 12 priority pathogens, with learnings extending to broader vaccine development.

Several respondents noted that the knowledge generated under UKVN was important during the COVID-19 pandemic. Specific contributions cited in strengthening R&D capabilities include:

- Development of new expertise in clinical trials across UK institutions and some LMIC partners
- Creation of tools and software to support emergency preparedness and response



Advances in bioprocessing platforms, diagnostic assays and immunology testing

Respondents also emphasised the UKVN's role in fostering new and existing collaborations within the UK and internationally. These collaborations facilitated the use of biocontainment facilities, exchange of best practices, and skills development through formal and informal engagements. UKVN-funded projects supported the training of many postdoctoral researchers – at least 35 according to one response, with the total likely substantially higher - across areas such as vaccinology, cell engineering and bioprocessing.

A few respondents further noted the UKVN's international contribution, particularly in generating evidence to inform policy during epidemics and during the COVID-19 pandemic.

While overall feedback was positive, a small number of respondents observed that not all R&D efforts led to follow-on research. One respondent suggested more network events could have improved collaborations and knowledge exchange across the UKVN 1.0.

## D.2 Scientific and technical barriers for technical implementation

When asked about the most frequently occurring project implementation challenges 'restrictions during the COVID-19 pandemic' was cited across 20 projects (51%) (see Figure 11). The onset of the COVID-19 pandemic was highly disruptive for research groups in a number of ways. The most prominent disruption noted by respondents was reduced access to facilities and equipment required to conduct research activities, such as high-biocontainment laboratories. These time pressures and use of equipment outside of regular maintenance service hours can influence the quality of technical results, requiring experiments to be repeated, leading to delays in project progression and cost increases. The pandemic also impacted teams' ability to work across borders, where activities such as shipping of samples were at times heavily delayed. Research was impacted as project funding and the work of many groups involved in the UKVN had to be redirected to COVID-19 response and vaccine research and development efforts. Challenges were experienced as PHE/UKHSA focused on pandemic response, and staffing was constrained as individuals had to move to new research positions, either for pandemic response efforts or following project timeline delays.



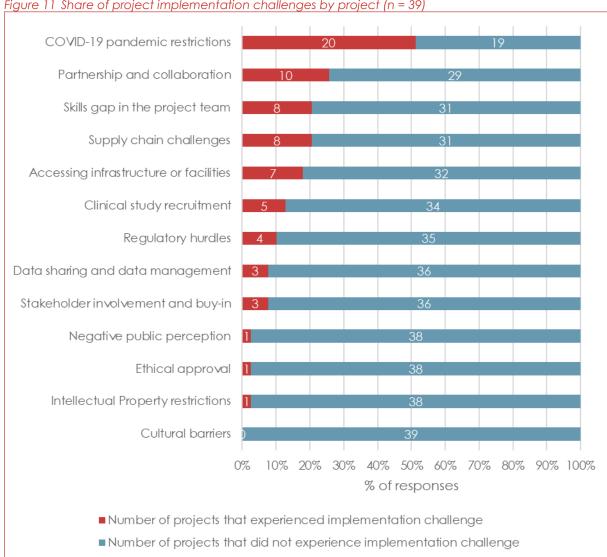


Figure 11 Share of project implementation challenges by project (n = 39)

Source: Survey data

Ten projects experienced 'partnership and collaboration challenges' which included issues with delivery of work by subcontractors and alignment of practices and protocols across institutions, as well as restraints on in-person activities during the COVID-19 pandemic. Other major issues experienced, such as skills gaps in the project team and supply chain challenges, were also noted to have been worsened by COVID-19 restrictions.

Respondents also experienced delays in starts to the project due to contract signing delays, which impacted project start-up phase activities such as recruitment and institutional account set up. Short duration of the funded period was also a cause for concern, which as well as providing little room for error in project timelines, it also does not provide security for earlycareer researchers who need to leave project roles.

Notably, Figure 11 shows that apart from challenges related to COVID-19, challenges in each of these areas were experienced by less than 25% of the 39 projects surveyed, indicating a general level of success in project implementation. Respondents from five projects stated that they did not experience any challenges at all in implementation, and a further three stated that barriers encountered were minor and overcome by the project team.



## D.3 UKVN 1.0 projects receiving follow-on funding

Follow-on funding suggests that UKVN 1.0-funded projects contributed to advancing research and development in key knowledge areas for priority pathogens. This funding may have helped vaccine candidates progress beyond pre-clinical stages or supported further investigation in domains such as One Health or epidemiology. This section examines the follow-on funding secured by UKVN 1.0 project team members.

Respondents from 25 projects (out of 39 covered in the survey, 64%) reported receiving follow-on funding. Table 14 lists the funder, the type of recipient organisation, and the amount awarded. Duplicate follow-on grants reported in the survey were removed, and additional information was obtained through online searches. The figures presented here are likely an underestimate, as survey responses did not cover all 76 UKVN 1.0 projects.

Overall, 33 follow-on projects were identified, totalling approximately £53m million in follow-on funding. A substantial share of this funding originated from UKVN 2.0 follow-on projects (£23m), CEPI (£19.8m) and UKRI (£6.4m).

For the UKVN 2.0 follow-on funding, a large proportion of funding identified was represented by the two EPSRC vaccine manufacturing hubs. The University of Oxford was the primary recipient of follow-on funding identified from CEPI. CEPI will provide up to \$80 million to support research and clinical development of vaccines for multiple UKVN1.0 priority pathogens, including MERS-CoV, Nipah, RVF, Lassa, as well as 'Disease X'.

Table 14 Value of follow-on funding identified by survey respondents, by funder and type of recipient organisation

Funder	Type of recipient organisation	Number of follow-on projects identified	GBP value
DHSC (UKVN 2.0)	University	3	£13,462,903
	National organisation (e.g., ministries, regulatory bodies, public health agencies)	3	£4,748,283
	Small and Medium Enterprise (SME) - business with fewer than 250 employees	2	£3,399,712
	Research Institute	1	£1,488,875
СЕРІ	University	3	£18,950,000
	National organisation (e.g., ministries, regulatory bodies, public health agencies)	1	£670,000
	Small and Medium Enterprise (SME) - business with fewer than 250 employees	1	£240,000
UKRI	Small and Medium Enterprise (SME) - business with fewer than 250 employees	10	£3,775,568
	Research Institute	3	£2,360,723
	National organisation (e.g., ministries, regulatory bodies, public health agencies)	1	£257,800
UKRI-NIFA (USA)	Research Institute	1	£1,311,934
Wellcome Trust	Research Institute	1	£1,200,000



US Department of Defence (USA)	Small and Medium Enterprise (SME) - business with fewer than 250 employees	1	£1,081,454
_	Research Institute	1	£285,154
European Union	Small and Medium Enterprise (SME) - business with fewer than 250 employees	1	£157,867
Total		33	£53,390,273

Source: Survey data. Respondents from three projects identified follow-on funding from private sources to progress research, however further details of this funding were not provided. Funding amounts provided in USD or Euros were converted to GBP via the following conversion rates: USD: 0.75, Euro = 0.84

## D.4 Barriers to receiving follow-on funding

Survey respondents also reflected on the barriers they faced in applications for further funding.

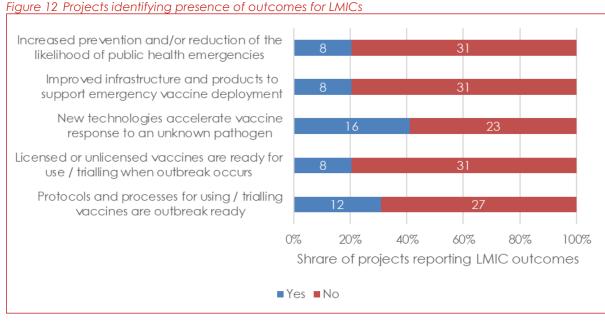
- Three projects attributed their lack of follow-on funding to challenges experienced in projects. Two projects could not access GMP manufacturing for pilot studies or phase I trials, while another attributed lack of follow-on funding to challenges onset by the COVID-19 pandemic and personnel turnover.
- Two projects deemed that their product was not commercially viable and could not justify
  investment in further development, either due to lack of scientific evidence to demonstrate
  market readiness, or due to the presence of a patent-protection in a comparator product
  by another company.
- Additionally, one respondent reflected that funding agencies had lost interest in funding adenovirus-based vaccines and considered them as non-fundable.

## D.5 Project outcomes for LMICs

We asked survey respondents to reflect on whether UKVN-funded projects contributed to relevant outcomes for LMICs. The survey provided five categories of potential outcomes, which along with the share of projects recognising that outcome, are listed in the figure below. The most frequent outcome identified from 16% of projects was that 'New technologies accelerated vaccine response to an unknown pathogen'. No considerable difference in outcomes was identified from projects across delivery partners.

Notably, 15 out of the 39 projects covered (38%) did not identify any outcomes for LMICs.





Source: Survey data

The survey also provided an open-text option to provide further details of any other outcomes for LMICs, where respondents outlined the following:

- Capacity building in LMICs (including lab-based training, experience in field trials, and protocol development) (5 projects)
- Development of treatments or diagnostics (2 projects)
- Contribution to standards / guidance (2 projects)
- Technology transfer agreements with LMIC organisations (2 projects)
- Improved public understanding and acceptance of vaccines (1 project)



# Appendix E Cost-benefit analysis of the ChAdOx platform

The UKVN Project 1.0 played an important role in supporting the development of the ChAdOx vaccine platform, which underpinned the creation of the Oxford-AstraZeneca vaccine. This appendix outlines the approach for conducting a cost-benefit analysis (CBA) to evaluate the impacts linked to this funding.

The study quantifies the global benefits of the first year of the Oxford-AstraZeneca COVID-19 vaccination programme in terms of the prevention of premature deaths from COVID-19 and reduction in quality of life from ward and Intensive Care Unit (ICU) hospitalisations.

The analysis estimates the value of UKVN 1.0's investment in the ChAdOx platform as a proportion of the total costs for developing and deploying the Oxford-AstraZeneca COVID-19 vaccine. This proportion is then applied this ratio to the vaccine's total estimated benefits to determine the share attributable to the UKVN 1.0. Finally, the analysis calculates a benefit-cost ratio by comparing this share of benefits with the cost of UKVN 1.0's investment in the ChAdOx platform.

Our findings show that for every £1 invested by the UKVN 1.0, the investment generated £43 in benefits by preventing premature death from COVID-19 and reducing quality of life impacts from hospitalisations.

# E.1 Methodological overview

#### E.1.1 Benefits

The section below briefly describes the impact channels included in the economic modelling framework. Further details on the methodology, assumptions, and limitations are available below in 'Further methodological details' section.

The health benefits of the Oxford-AstraZeneca vaccine are assessed in terms of its contributions to reducing COVID-19-related mortality and morbidity. The economic modelling includes monetary estimations for the following two types of benefits:

- Averted COVID-19 premature mortality. This measures the direct and indirect health benefits associated with the prevention of premature death from COVID-19. The modelling includes the direct impact to vaccinated individuals and the indirect benefits to nonvaccinated individuals who live in environments with reduced risk of infections due to high vaccination coverage.
- Averted COVID-19 hospitalisations. This includes the direct health benefits to vaccinated individuals associated with the prevention of illness from COVID-19 that results in ward and ICU hospitalisation.

Due to limitations in robust global data availability, the economic modelling does not include monetary estimations for the following types of benefits:

- Savings to the healthcare system. The economic modelling does not include a quantitative
  estimate of the financial savings to the healthcare system from preventing COVID-19
  associated ward and ICU hospitalisations, as well as treatments for post-COVID-19 recovery.
- **Health benefits to non-COVID-19 patients.** The analysis does not incorporate the benefits from averted elective care backlogs. As such, the health benefits to non-COVID-19 patients from the prevention of backlogs to healthcare treatments are not monetised.
- Contribution to other vaccine candidates. The ChAdOx vaccine platform has also been
  used to develop other vaccine candidates, both before and after the COVID-19
  pandemic. However, the wider health benefits are not formally included in the CBA



framework because of uncertainty around clinical trial outcomes and the absence of commercialised vaccines (other than the AstraZeneca COVID-19 vaccine) that have delivered measurable health impacts to date. Information on intermediate benefits achieved are presented separately and quantified where feasible.

Wider benefits to the economy. This CBA doesn't assign a monetary value to the economic
benefits that arose from lifting lockdown restrictions sooner. As such, economic benefits
from increased consumer spending, higher business revenues/survival, improved labour
market participation, school re-opening, and overall faster economic recovery are not
monetised.

#### E.1.2 Costs

The costs of the Oxford-AstraZeneca vaccine are assessed from the initial funding invested in the development of the ChAdOx platform through to the final delivery and administration of the vaccines. The economic modelling includes monetary estimations for the following four types of costs.

- **R&D costs.** This includes the value of R&D funding invested in the development of the ChAdOx platform from January 2004 to December 2019.
- R&D funding and manufacturing costs for the AstraZeneca vaccine. This includes the costs
  of clinical trials and the value of public funding invested in supporting the rapid expansion
  of vaccine production facilities to ensure the successful scaled-up manufacturing and
  distribution processes.
- **Procurement costs.** This includes the total cost of purchasing the Oxford-AstraZeneca vaccine, estimated by multiplying the number of doses administered by the price per dose. By November 2021, around 2 billion doses of the AstraZeneca vaccine were distributed at cost to 170 countries around the world<sup>5</sup>.
- **Delivery costs.** This includes the cost to the healthcare system in delivering the vaccine. The estimate includes 16 different cost components, such as the cost of PPE, human resources, transportation for outreach, waste management and more.

The attribution to the UKVN 1.0 is determined by measuring the extent to which UKVN 1.0-funded projects have contributed to the development of the vaccine. The section below provides further methodological details on each component of the economic framework used here.

# E.2 Further methodological details

#### E.2.1 Benefits

The CBA incorporates an estimate of the global health benefits from the Oxford-AstraZeneca COVID-19 vaccine up to December 2021. The sections below provide a detailed explanation of the methodology and data sources adopted for each impact channel.

#### E.2.2 Mortality impacts

The CBA incorporates the direct and indirect health benefits associated with the prevention of fatal COVID-19 cases. We utilised information from a published study by Watson et al (2022) which implemented a mathematical model of virus transmission and vaccination in 185

<sup>5</sup> https://www.astrazeneca.com/media-centre/press-releases/2021/two-billion-doses-of-astrazenecas-covid-19-vaccine-supplied-to-countries-across-the-world-less-than-12-months-after-first-approval.html#



countries to estimate the number of averted deaths due the COVID-19 vaccination programmes up to  $8^{th}$  December 2021.

In assessing the impact of vaccinations, the study simulated two scenarios:

- one without vaccines following the pandemic's transmission trend, and
- an observed scenario with reported vaccine administration rates in each country.

The number of deaths averted was calculated by subtracting estimated COVID-19 deaths in the observed scenario from those in the simulated counterfactual scenario without vaccines.

We estimated the aggregate number of deaths averted by leveraging existing evidence from this study on the number of deaths averted per 10,000 vaccine doses (first or second). We multiplied these figures by the number of Oxford-AstraZeneca vaccine doses administered in each country. Due to the lack of centralised data on the number of Oxford-AstraZeneca vaccines distributed to each individual country, we compiled data from various sources to estimate the global distribution? We utilised data from a GlobalData dataset with 43 high-income countries, a COVAX Facility report, and manual searches of published estimates in a sample of countries with large populations. Through this approach, we accounted for approximately 1.7 billion doses out of the 2 billion doses reported on AstraZeneca's website, reflecting the vaccine's widespread reach and impact across different regions<sup>8</sup>. Around 91% of our total estimate was distributed to low- and middle-income countries. From the list of countries, India has the highest number of AstraZeneca vaccine doses administered, with over one billion doses.

We quantified the health benefits in Years of Life Lost (YLL) terms, using published parameters in four different studies on the number of YLL per COVID-19 death<sup>9</sup> 10 11 12, covering 57 countries. The studies account for the demographic structure and the average life expectancy in each country, with deaths occurring at very old ages resulting in fewer life years lost compared to those at very young ages. For countries with missing data, we applied the average for their

<sup>&</sup>lt;sup>6</sup> Oliver J Watson, Gregory Barnsley, Jaspreet Toor, Alexandra B Hogan, Peter Winskill, Prof Azra C Ghani. Global impact of the first year of COVID-19 vaccination: a mathematical modelling study, The Lancet, 2022, doi:https://doi.org/10.1016/S1473-3099(22)00320-6, <a href="https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext">https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00320-6/fulltext</a>

<sup>&</sup>lt;sup>7</sup> The study team utilised GlobalData on the number of COVID-19 vaccine doses administered by manufacture in 43 high and upper-middle income countries, available here: <a href="https://ourworldindata.org/grapher/covid-vaccine-doses-by-manufacturer">https://ourworldindata.org/grapher/covid-vaccine-doses-by-manufacturer</a>

We combined figures from GlabalData with published data on the number of AstraZeneca vaccines delivered to COVAX Facility participants up to May 2021, available here: <a href="https://cdn.who.int/media/docs/default-source/3rd-edl-submissions/covax-first-round-allocation-of-az-and-sii-az---overview-tablev2.pdf">https://cdn.who.int/media/docs/default-source/3rd-edl-submissions/covax-first-round-allocation-of-az-and-sii-az---overview-tablev2.pdf</a>

To fill in remaining gaps in the data, the study team conducted further manual online searches on the number of AstraZeneca vaccines delivered per country. This manual review was done for countries with high population figures, including the UK, India, Vietnam, Bangladesh, Brazil, Egypt, Vietnam, Australia, and Thailand.

https://www.astrazeneca.com/media-centre/press-releases/2021/two-billion-doses-of-astrazenecas-covid-19vaccine-supplied-to-countries-across-the-world-less-than-12-months-after-first-approval.html#

<sup>9</sup> Years of life lost to COVID-19 in 81 countries, https://www.nature.com/articles/s41598-021-83040-3

<sup>&</sup>lt;sup>10</sup> Years of life lost to COVID-19 in 20 countries, <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC8877807/">https://pmc.ncbi.nlm.nih.gov/articles/PMC8877807/</a>

<sup>&</sup>lt;sup>11</sup> Premature mortality attributable to COVID-19: potential years of life lost in 17 countries around the world, January–August 2020, Premature mortality attributable to COVID-19: potential years of life lost in 17 countries around the world, January–August 2020 | BMC Public Health | Full Text

<sup>&</sup>lt;sup>12</sup> The mortality burden related to COVID-19, <a href="https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1378229/full">https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2024.1378229/full</a>



income group. For instance, evidence from the studies suggests that, on average, high income countries lost 12 years of life per COVID-19 death, compared to almost double that figure in low-income countries, at 23 years. This reflects differences in demographic structures and healthcare systems in different countries.

To monetise the health benefits, the total YLL saved was converted into monetary terms by applying published estimates of cost-effectiveness thresholds per quality-adjusted life years (QALY), using evidence from 174 countries<sup>13</sup>. As before, where data was not available for a specific country, we applied the average for the income group.

It is important to note that this approach offers a way of determining whether the health gains offered by a health intervention are sufficiently large relative to the costs for the intervention. As such cost-effectiveness thresholds, express the efficiency of a given intervention in terms of additional costs per unit of additional benefit (frequently measured in QALY). They do not represent a measure of a value of life, and it should not be interpreted as such.

It is also important to note that the Watson et al (2022) study focuses exclusively on the first year of vaccinations. According to the study, by the end of the study period, 56% of the global population had received at least one dose of a COVID-19 vaccine and 46% estimated had received two doses. While the number of Oxford-AstraZeneca vaccines administered in advanced countries has shown little increase beyond 8th December 2021, the situation in developing countries remains is less clear due to limited data on vaccine doses administered by manufacturer.

#### E.2.3 Morbidity impacts

While the number of averted deaths associated with the vaccine programme have been widely reported in studies with a global focus, there has been much less focus on the health benefits of averting non-fatal cases. Estimating the morbidity impacts is further complicated by the different severity profiles which can range from mild, short-term cases to severe illness necessitating ward or ICU hospitalisation and, in some instances, leading to persistent symptoms (i.e., long COVID).

To estimate the number of averted morbidity events, we used data on the number of observed ward and ICU hospitalisations, vaccine effectiveness and vaccine coverage in each country. The estimates account for the weeks of observations and the number of doses received, as follows:

$$Number_{averted\ w} = Number_{observed\ w}\ X\ \frac{\sum_{k=1}^{k=2} VC_{w,k}\ X\ VE_k}{1-(\sum_{k=1}^{k=2} VC_{w,k}\ X\ VE_k)}$$

Where  $VC_{w,k}$  represents the vaccine coverage of exactly k dosage in week w and the term  $(VC_{w,k} \times VE_{w,k})$  represents the proportion of the population that is protected by the vaccination. We used the average effectiveness rate against hospitalisations across three different variants (i.e., Delta, Alpha, and Gamma), for partial and full vaccination schedule (i.e., one or two doses).<sup>14</sup>

<sup>&</sup>lt;sup>13</sup> Determining the efficiency path to universal health coverage: cost-effectiveness thresholds for 174 countries based on growth in life expectancy and health expenditures, <a href="https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(23)00162-6.pdf">https://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(23)00162-6.pdf</a>

<sup>14</sup> Effectiveness rates for AstraZeneca vaccine, <a href="https://en.wikipedia.org/wiki/Oxford-AstraZeneca\_COVID-19\_vaccine">https://en.wikipedia.org/wiki/Oxford-AstraZeneca\_COVID-19\_vaccine</a>



Unlike the counterfactual modelling described in the Watson et al (2022) study, this method only considers the direct effects of vaccination on outcomes, excluding indirect effects on virus transmission. Therefore, it provides a conservative estimate of the true number of averted events.

We note that while COVID-19 hospitalisation data is readily available for upper-middle-income countries, the same data is not consistently available for low-income countries<sup>15</sup>. To address this gap, we applied the ratio of hospitalisations averted to deaths averted from data in high-income countries where data was available. The modelling assumed that the same ratio applies to low- and middle-income countries to estimate the number of hospitalisations averted. This approach is subject to limitations, including differences in healthcare infrastructure, demographic profiles, and disease burden between regions.

The morbidity impacts were quantified in QALYs using published parameters on the number of QALYs lost per COVID-19 case (per day)<sup>16</sup>. We assume that the median length of hospital stay is 7 days in ward and 10 days in ICU, and the reduction in quality of life persists during the length of stay in hospital based on data available on hospitalisations<sup>17</sup>. Multiplying the median length of stay by the estimated QALY loss per day gives:

- 0.01151 QALY loss per ward hospital stay and
- 0.01644 QALY loss per ICU hospital stay, applied consistently across each country in the analysis.

To monetise the health benefits, the total QALYs saved was converted into monetary terms by applying published estimates of cost-effectiveness thresholds per QALY for each country in the analysis.

#### E.2.4 Wider health benefits

While the ChAdOx platform has been most successfully applied in combating COVID-19, its underlying technology provides a strong foundation for future innovations in global health including cancer treatment 18 and the development of new vaccines that could benefit lowand middle-income countries.

We explored the use and value of the ChAdOx platform as an enabler for other vaccine candidates through a structured assessment of available clinical trials, pipeline reviews, and expert input. Although this analysis was systematic and evidence-based, it was not incorporated into the quantitative CBA estimates, as it was not possible to assign a fully monetised value to these benefits.

# E.2.5 Attributed mortality and morbidity health benefits to the UKVN 1.0

UKVN 1.0 played a role in supporting the development of the ChAdOx vaccine platform, which underpinned the creation of the Oxford-AstraZeneca vaccine. This achievement, however, was the culmination of over two decades of research and development (R&D) into the core

<sup>&</sup>lt;sup>15</sup> Weekly new hospital admissions for COVID-19, https://ourworldindata.org/grapher/weekly-hospital-admissions-covid

<sup>&</sup>lt;sup>16</sup> Basu A, Gandhay VJ. Quality-Adjusted Life-Year Losses Averted With Every COVID-19 Infection Prevented in the United States. Value Health. 2021 May;24(5):632-640. doi: 10.1016/j.jval.2020.11.013. Epub 2021 Mar 8. PMID: 33933231; PMCID: PMC7938736. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7938736/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7938736/</a>

<sup>&</sup>lt;sup>17</sup> Chart of the week: How long do COVID-19 patients spend in hospital, February 2021, https://www.nuffieldtrust.org.uk/resource/chart-of-the-week-how-long-do-covid-19-patients-spend-in-hospital

<sup>&</sup>lt;sup>18</sup> https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-vaccine-chemotherapy-and-an-immunotherapy-for-non-small-cell-lung-cancer-and-squamous-oesophageal-cancer



technology, funded by national and international organisations. As such, a key challenge for the CBA analysis was estimating the UKVN's attribution to the development of a vaccine platform that has received a multitude of public and private funding for development before the vaccine was ultimately distributed worldwide.

To determine the attribution of health benefits to the UKVN specifically, we used the monitoring data to identify the value of UKVN funded projects that have contributed to the development of the ChAdOx platform. This was compared to the total funding for R&D of the ChAdOx technology and the COVID-19 vaccine's development. Due to the complexity of tracing the total value of contributions from all funding bodies (incl. non-UKVN), our analysis relied on published data. A study by Cross et al. (2021) evaluated the total funding for the development of the ChAdOx technology and the Oxford-AstraZeneca vaccine, producing two separate analyses based on distinct methodologies<sup>19</sup>. The first method relies on examining funding disclosures in academic publications, while the second method analyses data obtained through Freedom of Information (FOI) requests to the University of Oxford. The FOI approach used values of the grants received by the principal investigators involved in the development of the ChAdOx vaccine platform, Professor Sarah Gilbert and Professor Adrian Hill, from 2004 to 2021.

For the purposes of our study, the value of health benefits attributed to UKVN 1.0 was determined by the proportion of funding provided by UKVN 1.0 compared to the total R&D funding and other costs associated with the delivery of the Oxford-AstraZeneca vaccine. The rationale is that the vaccine's benefits (including the proportion attributed to the UKVN 1.0) would not have occurred without the total funding invested in its development.

# E.3 Costs of the ChAdOx platform

In the CBA framework, the total cost estimates include the full economic investment required to achieve the benefits, regardless of who provided the funding. As such, the model will consider the total cost of the AstraZeneca vaccination effort in full, not just the proportion of the cost funded by the UKVN.

The total cost estimate for this study includes four different components:

• **R&D funding for the ChAdOx platform.** We estimated the value of R&D funding secured for the development of the ChAdOx platform using evidence from the literature<sup>20</sup>. Using evidence from the Cross et al (2021) study, we estimated the value of grant funding received by the principal investigators involved in the development of the ChAdOx vaccine platform, Professor Sarah Gilbert and Professor Adrian Hill, from January 2004 to December 2019.

The value of R&D funding for the ChAdOx platform also includes an estimate of £36 million private equity funding raised by Vaccitech, the spinout company led by Sarah Gilbert and Adrian Hill (now renamed to Barinthus Biotherapeutics plc)<sup>21</sup>. The specific share of this

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<sup>&</sup>lt;sup>19</sup> Cross S, Rho Y, Reddy H, Pepperrell T, Rodgers F, Osborne R, Eni-Olotu A, Banerjee R, Wimmer S, Keestra S. Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? BMJ Glob Health. 2021 Dec;6(12):e007321. doi: 10.1136/bmjgh-2021-007321. PMID: 34937701; PMCID: PMC8704023. https://pubmed.ncbi.nlm.nih.gov/34937701/

<sup>&</sup>lt;sup>20</sup> Cross S, Rho Y, Reddy H, et al. Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine? BMJ Global Health 2021;6:e007321. doi:10.1136/ bmjgh-2021-007321 <a href="https://gh.bmj.com/content/bmjgh/6/12/e007321.full.pdf">https://gh.bmj.com/content/bmjgh/6/12/e007321.full.pdf</a>

<sup>&</sup>lt;sup>21</sup> How the 'Oxford' Covid-19 vaccine became the 'AstraZeneca' Covid-19 vaccine, <a href="https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf">https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf</a>



funding allocated to support COVID-19 research is unclear, but have included the total cost as the funding was instrumental in expanding the business and enhancing its lab infrastructure, which were essential for the development of the AstraZeneca vaccine, as well as for other candidates.

• R&D funding and manufacturing costs for the Oxford-AstraZeneca vaccine. This includes the costs of clinical trials and the value of public funding invested in supporting the rapid expansion of vaccine production facilities to ensure the successful scaled-up manufacturing and distribution processes. Estimating the value of public funding invested in the manufacturing of the AstraZeneca vaccine is challenging due to lack of transparency and consistently reported data from all countries. Reported figures often lump together different components, making it difficult to disaggregate the cost of certain activities.

We rely on data compiled from publicly available sources from individual countries to determine the overall costs, noting that the final estimates are likely to be underestimated due to lack of available data on the aggregate costs. Our cost estimate includes the following figures:

- £35.7 million funding obtained by Sarah Gilbert and Adrian Hill since 2020 to support the development of the Oxford-AstraZeneca vaccine. Most of this funding, £32 million, came from the Department of Health and Social Care to support Phase I/II/III clinical trials. The figures were sourced from the Cross at el study (2021) for the period of January 2020 and December 2023<sup>22</sup>.
- £65.5 million from the UK government since March 2020 to support the early manufacturing of the vaccine, plus further £2.6 million through NIHR and UKRI for research of the vaccine and £8.75 million to set up the rapid deployment facility at Oxford Biomedica to manufacture the vaccine at scale. <sup>23</sup>
- £324 million (or \$400 million) grant value to the Serum Institute of India (SII) to manufacture the Oxford-AstraZeneca vaccine.<sup>24</sup>

The US Biomedical Advanced Research and Development Authority (BARDA) announced \$1.2 billion funding for the advanced development and manufacturing of the Oxford-AstraZeneca COVID-19 vaccine. Published articles suggest that the funding will support advanced clinical studies, vaccine manufacturing technology transfers, process development, scaled-up manufacturing, and other development activities.<sup>25</sup> <sup>26</sup> The contract also includes the purchase of 300 million doses, at a price of \$4 per dose as reported in other sources<sup>27</sup>. As the allocation of funding for different activities is not clear,

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<sup>&</sup>lt;sup>22</sup> Cross S, Rho Y, Reddy H, et al. Who funded the research behind the Oxford–AstraZeneca COVID-19 vaccine? BMJ Global Health 2021;6:e007321. doi:10.1136/bmjgh-2021-007321 <a href="https://gh.bmj.com/content/bmjgh/6/12/e007321.full.pdf">https://gh.bmj.com/content/bmjgh/6/12/e007321.full.pdf</a>

<sup>&</sup>lt;sup>23</sup> One year anniversary of UK deploying Oxford-AstraZeneca vaccine, Jan 2022, <a href="https://www.gov.uk/government/news/one-year-anniversary-of-uk-deploying-oxford-astrazeneca-vaccine">https://www.gov.uk/government/news/one-year-anniversary-of-uk-deploying-oxford-astrazeneca-vaccine</a>

<sup>&</sup>lt;sup>24</sup> India to fund capacity boost at Serum Institute, Bharat Biotech as vaccines run short, April 2021, <a href="https://www.reuters.com/world/india/india-fund-capacity-boost-serum-institute-vaccines-run-short-source-2021-04-19/">https://www.reuters.com/world/india/india-fund-capacity-boost-serum-institute-vaccines-run-short-source-2021-04-19/</a>

<sup>&</sup>lt;sup>25</sup> BARDA Commits \$1.2 Billion to AstraZeneca Vaccine Program, May 2020, https://www.biopharminternational.com/view/barda-commits-12-billion-astrazeneca-vaccine-program-0

<sup>&</sup>lt;sup>24</sup> U.S. secures 300 million doses of potential AstraZeneca COVID-19 vaccine, May 2020, https://www.reuters.com/article/world/us-secures-300-million-doses-of-potential-astrazeneca-covid-19-vaccine-idUSKBN22X0.18/

<sup>&</sup>lt;sup>27</sup> Covid-19: Countries are learning what others paid for vaccines, 2021, <a href="https://www.bmj.com/content/372/bmj.n281">https://www.bmj.com/content/372/bmj.n281</a>



we assume that most of the funding was allocated towards procurement costs. As such, the figure is not included in the analysis to avoid duplication with the procurement costs detailed below.

As the Oxford-AstraZeneca vaccine was sold at cost up to the end of 2021, we assume that that the price paid per dose covers the private cost incurred by AstraZeneca to produce, clinically test, and distribute the vaccine<sup>28</sup> <sup>29</sup>. As such, our analysis only incorporates the value of public funding invested in the manufacturing and distribution of the vaccine as we assume that any private costs invested by the company were recuperated by the sales revenue.

- **Procurement costs.** We estimate the total procurement costs by multiplying the number of AstraZeneca vaccines administered per country by the price cost per vaccine dose. In our analysis, the price per AstraZeneca vaccine dose ranges from £1.5 in the EU to £4.3 in South Africa<sup>30 31</sup>. Where country-level data was unavailable, we estimated the cost per dose using an average within the range reported online, from \$3 to \$5 per dose<sup>32</sup>. The Oxford-AstraZeneca vaccine is much less expensive compared to many other COVID-19 vaccines, resulting in procurement costs that are lower compared to other vaccine alternatives.
- Delivery costs. We used published estimates on the total cost of delivering the COVID-19 vaccination programme in 133 low-and middle-income countries<sup>33</sup>. The study provides country-levels estimates on the delivery cost per dose for 16 different cost components, such as PPE, human resource costs, transportation for outreach, waste management etc. The number of Oxford-AstraZeneca vaccine doses delivered in each country was multiplied by unit costs per dose to estimate total costs for each country. We removed the unit cost of cold chain deployment because the vials that contain Astra's vaccine can be kept in a normal refrigerator.

Due to limited data for all high-income countries, we assumed that the delivery cost per dose in these countries was equivalent to the estimated cost for upper-middle-income countries. This assumption is supported by a study on vaccine delivery costs in the UK, which suggests that the cost per dose aligns with estimates for upper-middle-income countries, reinforcing the validity of our approach<sup>34</sup>.

<sup>30</sup> https://en.wikipedia.org/wiki/Deployment of COVID-19 vaccines

<sup>28</sup> https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-to-supply-europe-with-up-to-400-million-doses-of-oxford-universitys-vaccine-at-no-profit.html#

<sup>&</sup>lt;sup>29</sup> https://www.bbc.co.uk/news/business-59256223

<sup>31</sup> https://www.straitstimes.com/world/south-africa-to-pay-big-premium-for-astrazeneca-covid-19-vaccine-from-indias-sii

<sup>32</sup> Converted to GBP using an exchange rate of \$1 = £0.81

<sup>&</sup>lt;sup>33</sup> Unicef, Costs and predicted financing gap to deliver COVID-19 vaccines in 133 low- and middle-income countries <a href="https://www.unicef.org/media/114216/file/Costs-and-Predicted-Financing-Gap-to-Deliver-COVID-19-Vaccines-in-133-Low-and-Middle-Income-Countries.pdf">https://www.unicef.org/media/114216/file/Costs-and-Predicted-Financing-Gap-to-Deliver-COVID-19-Vaccines-in-133-Low-and-Middle-Income-Countries.pdf</a>

<sup>&</sup>lt;sup>34</sup> The rollout of the COVID-19 vaccination programme in England, 2022, <a href="https://www.nao.org.uk/reports/the-roll-out-of-the-covid-19-vaccine-in-england/#downloads">https://www.nao.org.uk/reports/the-roll-out-of-the-covid-19-vaccine-in-england/#downloads</a>



# E.4 Findings

#### E.4.1 Benefits

#### E.4.1.1 Mortality impacts

We estimate that the Oxford-AstraZeneca vaccine prevented approximately 4.3 million premature COVID-19 deaths globally up to 8 December, 2021.<sup>35</sup> Of these, around 3.7 million occurred in low- and middle-income countries, representing 84% of the total deaths averted.

Based on estimates of life years lost per COVID-19 death, we estimate that the Oxford-AstraZeneca vaccine prevented the loss of approximately 86 million years of life within the first year of vaccination. Of these, around 78 million years were saved in low- and middle-income countries, representing 91% of the total years of life saved.

Using country-specific monetary estimates of cost-effectiveness thresholds, we estimate that the Oxford-AstraZeneca's vaccine has generated £293 billion in value through the prevention of premature mortality.

When examining the distribution of monetised health-benefits across the four income groups, it is important to note that the differences in values are driven by the cost-effectives thresholds (CET) per QALY applied in this study. CETs provide a standardised way of assessing whether a health intervention should be adopted or prioritised in national health policy. These thresholds are a statistical tool and should not be interpreted as a measure of the value of a human life. Because health budgets in LMICs are generally more constrained, their CET values are lower. This means that vaccine investments in LMICs are more likely to displace other life-saving interventions compared to HICs, where healthcare budgets are larger. While the willingness to pay per QALY is lower in LMICs, this does not imply that lives in these countries are valued less in human terms.

When applying a single population-weighted average cost effectiveness threshold across all countries, the estimated monetary value of total averted COVID-19 deaths is £749 billion. Of this total, 77% is attributable to low- and middle-income countries, compared with only 11% when country-specific QALY thresholds are applied).

Table 15 Mortality benefits of the Oxford-AstraZeneca vaccine, by country income category

	Deaths averted, per 10k vaccine doses administered	Oxford- AstraZeneca doses administered, million	Deaths averted due to Oxford- AstraZeneca vaccine, million	Total years of life saved, million	Monetary value of total averted COVID-19 deaths, GBP million
Low income	3	31	0.01	0.19	28
Lower middle income	20	1,263	3.04	66	31,215
Upper middle income	23	240	0.62	12	75,096

<sup>&</sup>lt;sup>35</sup> Another study by Airfinity, using a different methodology, estimated that the Oxford-AstraZeneca vaccine saved 6.3 million lives worldwide, around 2 million more than the estimate presented in this study. For more information, <a href="https://www.ox.ac.uk/news/2022-07-15-oxford-vaccine-saved-most-lives-its-first-year-rollout">https://www.ox.ac.uk/news/2022-07-15-oxford-vaccine-saved-most-lives-its-first-year-rollout</a>



High income	37	159	0.68	8	186,404
World	26	1,693	4.35	86	292,744

Source: Technopolis analysis using data sources referenced in the methodology section

#### E.4.1.2 Morbidity impacts

Globally, the Oxford-AstraZeneca vaccination programme directly averted over 2 million ward and 329,985 ICU hospitalisations up to 8<sup>th</sup> December 2021.

We estimate the monetary value of avoiding morbidity impacts from reduced quality of life following COVID-19 hospitalisation at £133 million. The majority of this benefit (£105 million) comes from preventing ward admissions.

This estimate does not account for the indirect health benefits to unvaccinated individuals who may experience lower hospitalisation rates due to reduced infection and transmission. As a result, the figure likely underestimates the total impact, capturing only the direct health benefits. Additionally, most countries in our analysis lacked data on weekly hospital admissions, so our estimates rely on modelling assumptions. Specifically, we calculated the average number of averted hospitalisations per averted death for countries with both data points and applied this ratio to countries that only had data on averted deaths.

Table 16 Number of averted COVID-19 ward and ICU hospitalisations due to the Oxford-AstraZeneca vaccine

	Number of averted COVID-19 ward hospitalisations	Number of averted COVID-19 ICU hospitalisations	Value of total averted COVID-19 ward hospitalisations	Value of total averted COVID- 19 ICU hospitalisations
Low income	3,876	621	6,642	1,521
Lower middle income	1,467,514	235,155	8,032,993	1,838,874
Upper middle income	302,634	47,769	22,447,601	5,096,645
High income	239,988	46,440	75,160,123	20,402,290
World	2,014,012	329,985	105,647,360	27,339,330

Source: Technopolis analysis using data sources referenced in the methodology section

#### E.4.1.3 Wider health benefits

Our analysis of ClinicalTrials.gov data indicates that over 116 trials have investigated ChAdOx-based vaccine candidates against a broad range of diseases. While COVID-19 represents the largest proportion of trials (n = 76), the ChAdOx platform has been utilised for the development of 11 of the 12 UKVN priority pathogens (see final report), other infectious diseases relevant to



LMICs (e.g., tuberculosis, HIV/AIDS, malaria), as well as to immune-oncology vaccines (e.g. targeting prostate cancer).

In March 2021, M&G announced a \$168 million investment in Vaccitech, the University of Oxford spinout company led by the principal investigators involved in the development of the ChAdOx vaccine platform, Professor Sarah Gilbert and Professor Adrian Hill. The funding will be used to explore how the ChAdOx platform can be utilised for infectious diseases and prostate cancer.<sup>36</sup>

#### E.4.2 Total costs

We estimate that the total cost associated with the development and delivery of the Oxford-AstraZeneca vaccine is £6.8 billion globally.

Most of the total cost is associated with delivery costs (£3.5 billion) and procurement costs (£2.8 billion). An additional £475 million of public funding was invested to support clinical studies, scaled-up manufacturing, and distribution costs.

Importantly, the total R&D cost of the ChAdOx1 platform is estimated to be £96 million, with the UK Vaccine Network contributing approximately £32 million, or 33% of the total vaccine platform development cost. This is notable as the availability of the ChAdOx1 vaccine platform was critical to rapidly developing one of the first COVID-19 vaccines that was granted emergency use listing by the World Health Organisation.

Table 17 Total estimated costs for delivering the AstraZeneca vaccination programme globally, up to December 2021

Cost type	Costs in GBP
R&D costs for the ChAdOx platform	96,004,135
R&D and manufacturing costs from the AstraZeneca vaccine	474,518,221
Delivery cost	3,450,566,793
Procurement cost	2,753,890,106
Total costs	6,774,979,256

Source: Technopolis analysis using data sources referenced in the methodology section

#### E.4.3 Benefit – Cost ratio

To determine the attribution of health benefits to the UKVN specifically, we used monitoring data on the value of UKVN funded projects that have contributed to the development of the ChAdOx platform. This was compared to the total cost of developing and delivering the Oxford-AstraZeneca vaccine.

Our findings indicate that the UKVN has contributed £36 million to the development of the ChAdOx platform and AstraZeneca vaccine, representing 0.5% of the total cost of the

<sup>36</sup> https://www.mandg.com/news-and-media/press-releases/mandg-plc/2021/17-03-2021



vaccination programme. As such, we assume that the equivalent share of the observed health benefits from the Oxford-AstraZeneca vaccination are attributed to UKVN, resulting in a total benefit of £1.6 billion.

Our findings show that for every £1 invested by UKVN 1.0, approximately £43 in benefits was generated by preventing premature COVID-19 deaths and reducing quality of life losses from ward and ICU hospitalisations.

# E.5 Study limitations

There are six main limitation and caveats to our analysis:

- Missing data. The study is limited by the availability of global data on COVID-19 variables, especially in low-income countries where data availability is more limited. Consequently, the modelling incorporates assumptions based on the information from countries with available data. Where country-level data was missing, the model estimated an average from countries with available data and assumed it to be representative of those without data. For example, to estimate the number of averted hospitalisations in countries without data on the hospital admissions, we used the ratio of hospitalisations averted to deaths averted from high-income countries and applied it to low- and middle-income countries.
- Vaccine effectiveness. To estimate the number of averted deaths per 10k vaccines, the Watson et al study (2022) used the vaccine efficacy data according to the vaccine types known to be predominantly used in each country. As such, the figures presented in the study reflect the entire vaccination program in each country, rather than presenting a closer examination of AstraZeneca's contributions alone. The evidence from clinical trials suggests that the Oxford-AstraZeneca vaccine is 65-75% effective at preventing symptomatic COVID-19 disease with the Delta variant, compared to the more efficacious mRNA vaccines (80-90% for Pfizer-BioNTech, and 90-99% for Moderna)<sup>37</sup>. However, when we consider mortality and sever cases that result in hospitalisations, the effectiveness rates are similar across the three vaccine types, ranging from 90-95%.
- Assessment period. The assessment period for our study includes the first year of vaccination efforts up to 8th December 2021, as implemented in the Watson et al study. Since the counterfactual scenario is modelled rather than observed, we considered this approach appropriate given the uncertainty involved in estimating what would have happened without vaccinations. Natural immunity, potential developments of non-pharmaceutical interventions, and the spread of new variants would have likely altered the course of the pandemic from that assumed under a modelled counterfactual scenario, making comparisons between actual and simulated 'no-vaccination' scenarios more uncertain over time.

However, one key limitation of our approach is that the vaccination efforts continued beyond this period, especially in low-income countries where the vaccination roll-out was slower. As shown in Figure 13, up to 8<sup>th</sup> December 2021, the total number of people who received all doses prescribed by the initial vaccination protocol as a share of the total population was significantly higher in high income (68%) and upper-middle income countries (64%), compared to lower-middle-income (28%) and low-income countries (6%).

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<sup>&</sup>lt;sup>37</sup> Vaccine effectiveness rates,

https://assets.publishing.service.gov.uk/media/615edd16e90e07197a68c1c8/Vaccine\_surveillance\_report - week\_40.pdf



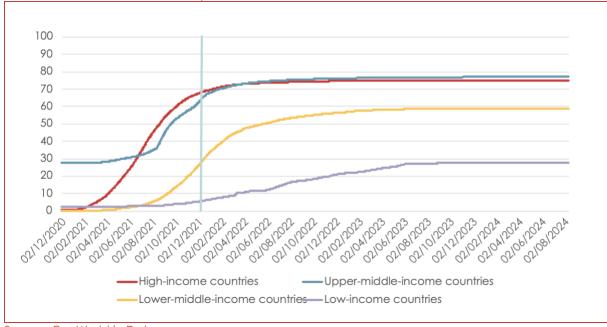


Figure 13 Share of people who have completed the initial COVID-19 vaccination protocol, up to 8th December 2021 and beyond

Source: Our World in Data

• Measuring R&D costs. The lack of transparency on R&D funding is a prevailing issue. The Cross et al (2021) study focuses on identifying the funding sources behind the Oxford-AstraZeneca vaccine research conducted at the University of Oxford (specifically grants received by SG and AH). One of the main limitations outlined in the study is that FOIs requests must take a maximum of 18 hours to fulfil, limiting the scope of data that can be provided. Furthermore, the descriptions of some grants identified in the FOI request were considered too vague to attribute them to the development of the ChAdOx platform specifically, resulting in their removal.

Another key limitation outlined in the Cross et al (2021) study is that the analysis excludes the value of further contributions for the development and manufacturing of the AstraZeneca vaccine, beyond the initial investment provided to the University of Oxford. For this reason, our CBA analysis relied on separate estimates published in the wider literature which limits the robustness of our findings as the total manufacturing costs are likely to be underestimated due to lack of available data that is consistently recorded across countries. As such, the R&D funding costs are likely higher than those reported in the study.

- Funding sources of vaccine procurement. Another limitation of this study is the uncertainty around the funding sources for vaccine procurement and distribution. Many low-income countries received financial support and vaccine donations from high-income countries and global initiatives, making it difficult to accurately determine the benefit-cost ratios across different income groups. Since the true cost burden was shared across multiple countries, attributing expenditures to specific countries or income groups is challenging.
- Delivered vs administered doses. One limitation of this study is the lack of globally available
  data on vaccine doses administered per manufacturer. As a result, our approach relies on
  a combination of global vaccine administration data by country from Our World in Data,
  COVAX data on doses delivered, and manual searches for countries with large populations.
  However, this method introduces uncertainty, as the latter two sources provide information
  on vaccine deliveries rather than actual administration. It is unclear what proportion of



delivered doses were ultimately used and what share of vaccines were wasted in each country. This limitation may affect the accuracy of our estimates regarding vaccine uptake and distribution across countries.



# Appendix F Survey and interview questionnaires

# F.1 Survey questionnaire

<u>Technopolis</u> and <u>Triple Line Consulting</u> have been commissioned by the UK's National Institute for Health and Care Research (NIHR), on behalf of the Department for Health and Social Care (DHSC), to conduct an **independent impact and process evaluation** of the first phase of the UK Vaccine Network (UKVN) Project (2016 to 2023). The evaluation will identify learnings for the recently launched UKVN Project 2.0 and inform future investments.

#### About the survey

The survey is aimed at individuals acting as project leads (principal investigators) and representing partner organisations involved in the UKVN Project 1.0 (from now on referred to as 'the UVKN programme'). Please note that funded projects would have been contracted through a dedicated delivery partner of the UKVN programme: Biotechnology and Biological Sciences Research Council (BBSRC), Engineering and Physical Sciences Research Council (ESPRC), Innovate UK, or the National Institute for Health and Care Research (NIHR CCF and NIHR NETSCC). This survey is an important tool to gather the latest evidence on the outputs, outcomes and impacts achieved by funded projects in a consistent way and learn from implementation challenges and good practices. The survey is designed to minimise burden on you, and we hope that you will contribute to the study on exploring the impact of the UKVN programme.

# Completing the survey and anonymity

Please note the survey will close on the <u>8 January 2025</u>.

The survey will take around 30 minutes to complete for project leads and around 15 minutes for project partners for one project. Project partners are requested to complete one survey per project participation.

All responses and associated personal information will be treated in strict confidence, in line with UK legislation on data protection rules. Please note that the funders of the UKVN programme have no access to the survey platform or your completed questionnaire. We are independent research organisations, and information gathered will only be reported in an aggregate and anonymised form to the funders of the UKVN programme. Where answers may be attributable, we will contact you to ask your permission before sharing such information.

If you wish to contact the independent review team, please email Dr Peter Varnai, co-lead of the evaluation, at <a href="mailto:ukvn-evaluation@technopolis-group.com">ukvn-evaluation@technopolis-group.com</a>. Thank you for taking the time to complete the survey – your participation is extremely important to inform the independent evaluation.

Before you begin, please make sure that your browser is maximised. It's easy to navigate through the questionnaire: just click on the answer or answers that apply for each question. You may need to use the scroll bar to see the next question. Comment boxes for open-text answers can be expanded as needed by dragging the bottom right corner. To continue, click on the next button at the bottom of each page. While your browser is open you can go backwards and forwards in the survey.

Please click 'Next Page' to enter the survey.

# Next page

About you and your UVKN-funded project



#### [Routing = All]

 To start, please tell us whether you were a project lead or a partner in the UKVN-funded project you are completing this survey for? For your project title(s) and other project details, please refer to the cover email with the link to this survey. If you are unsure, please get in contact with the evaluation team for clarifications.

# [single-choice question] [compulsory question]

- Project Lead
- Partner (including subcontractors)

# [Routing = All]

2. Please provide the name of the organisation where you were employed at the time of the project implementation:

[Comment box] [compulsory question]

#### [Routing = All]

3. Please indicate the organisation type:

[single-choice question] [compulsory question]

- University
- Research Institute
- Small and Medium Enterprise (SME) business with fewer than 250 employees
- Large Enterprise business with 250 employees or more
- National organisation (e.g., ministries, regulatory bodies, public health agencies)
- International organisation (e.g., WHO)
- Healthcare provider (e.g., hospital facilities)
- Charity
- Other (please specify):

## [Routing = All]

4. Where is this organisation based?

[drop-down list of countries with UK at the top] [compulsory question]

"Please provide the city or town (municipality) where this organisation is based:" [Comment Box label]

# Next page

We will ask you questions about your project(s) funded under the UKVN 1.0 programme.

**Important:** to facilitate responses for **people involved in more than one grant**, we ask you to combine your answer by project. We define 'project' as one or more grants supporting activities involving the same research focus and/or pathogen. For example, those awarded funding in a Stage 1 competition and, subsequently, received follow-on funding in a Stage 2 competition, for the same pathogen, we consider these two grants as one project.



For those awarded more than one grant for unrelated research projects, please provide information separately for the two projects. (For those with three or more projects, we indicated in the cover email the two project titles we would like you to consider in your survey response.)

#### [Routing = AII]

5. How many projects are you providing information for in this survey?

#### [Single-choice question] [compulsory question]

- One project (may involve two linked grants)
- Two projects

#### \*\*Important\*\*

[Routing = Project Details, Project findings and outputs, and Project Outcomes and Impacts will repeat if respondent selects 'Two projects' in the above question]

# Next page

#### **Project details**

Please provide answers to the following questions related to a single project (may involve two linked grants) below.

#### [Routing = All]

6. To help you select the project grant reference, please confirm which funder awarded the grant(s) for your project. If you are not sure, please check your invitation email.

#### [single-choice question] [compulsory question]

- Biotechnology and Biological Sciences Research Council (BBSRC)
- Engineering and Physical Sciences Research Council (ESPRC)
- Innovate UK (IUK)
- National Institute for Health and Care Research (NIHR)

# Next page

#### [Routing = AII]

[Routing 2 = drop-down lists should be routed by delivery partner e.g. those selecting NIHR in Q6 should not see Innovate UK projects]

7. Please select from the dropdown list the project title and grant reference. If you are not sure, please check your invitation email.

[drop-down list of projects routed by delivery partner] [compulsory question]

#### For BBSRC, EPSRC and NIHR:

8. If your project includes a follow-on grant related to the selected project, please provide the title and grant reference (if known).

[comment box]

#### For Innovate UK:



9. If your project includes a follow-on grant related to the selected project, please select it from the dropdown list below.

[drop-down list of projects routed by delivery partner]

If the follow-on grant is not listed above, please provide the title and grant reference.

[comment box]

#### [Routing = Project leads only]

10. Did the UKVN-funded project receive additional co-funding from other sources? [single-choice question] [compulsory question]

- Yes
- No
- Don't know

#### [Routing = Project leads only]

[Routing 2 = if 'No' / 'Don't know' to above question, skip/hide this question]

11. Please describe the level and source of co-funding:

[comment box]

# Next page

#### Project team

In this section we would like to explore the composition of the project team that was involved in the project implementation.

#### [Routing = Project Lead only]

12. Please provide the total number of project team members across **all organisations**. Please provide separate numbers for High-income countries and Low- and middle-income countries. Please include all research students, postdocs and other staff members (e.g., permanent researchers, technicians) who contributed to the implementation of the project. If you don't know the exact numbers, please provide best point estimates.

[Comment Box label]: "High-income countries"

[Comment Box label]: "Low- and middle-income countries

#### [Routing = AII]

13. Did you previously work with the lead/partner organisation(s) involved in this project? [single-choice question]

- Yes, I worked previously with all partners involved in this project
- Yes, I worked previously with some partners (but not all) involved in this project
- No, this was the first time I worked with these partners

# [Routing = All]



14. Please provide the total number of project team members **at your organisation**. Please include all research students, postdocs and other staff members (e.g., permanent researchers, technicians) who contributed to the implementation of the project. If you don't know the exact numbers, please provide best point estimates.

[comment box]

# Next page

# Project experience and learning

In this section, we would like to explore any challenge the project might have encountered, its effect on the project, and possible learnings.

#### [Routing = All]

15. Did you face any of the following challenges when implementing the project? Select all that apply:

# [tick-box question]

- Skills gap in the project team
- Partnership and collaboration challenges
- Lack of access to suitable infrastructure or facilities
- Issues with ethical approval
- Regulatory hurdles
- Issues with recruitment for clinical studies
- Supply chain challenges
- Data sharing and data management barriers
- Restricted Intellectual Property environment
- Cultural barriers
- Negative public perception and misinformation
- Issues with stakeholder involvement / buy-in
- Restrictions during the COVID-19 pandemic
- Other (please specify):

#### [Routing = All]

16. Please describe briefly any scientific / technical barrier(s) you encountered when implementing the project, and the impact these had on the project (e.g. reduced project scope or extended study timelines).

[comment box]

# Next page

#### Project findings and outputs

We received final reports for UKVN-funded projects, which include information on project outputs. In this section, we would like to check any new outputs that might have emerged since the project end.

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## [Routing = Project Lead only]

Vaccine R&D

We would like to start by mapping the progress of projects that contributed to developing vaccine candidate(s) onto the UKVN <u>Vaccine Development Map.</u>

17. Was the aim of your project to progress the development of a vaccine candidate? [single-choice question] [compulsory question]

- Yes
- No

[Routing = if 'No' in previous question, skip/hide next questions, go all the way to the end of vaccine development questions]

Here, we ask you about the R&D stage and detailed area of research of your UKVN-funded project.

18. Please select the R&D stage(s) applicable to your project. Please select more than one stage if your project progressed through these stages.

[tick-box question question] [compulsory question]

- Pre-clinical discovery
- Pre-clinical development
- Clinical development
- Other (please specify):

#### [Routing = Project lead Only, only those that select 'Other' in Q17]

19. Please describe more details about the R&D stage and area of research of your UKVN-funded project

[comment box]

# Next page

#### [Routing = if 'Pre-clinical discovery' in Q18, show next question, else, skip it]

You have selected 'Pre-clinical discovery'. The <u>UKVN Vaccine Development Map for Pre-Clinical Discovery</u> outlines the steps involved in this stage of development.

20. Please select all the step(s) that were conducted during the implementation of your UKVN-funded project.

#### [tick-box question]

- 0. Definition of target product profile
- 1. Human/livestock host immunology
- 2. Exploration of pathogen biology
- 3. Development of pathogen challenge model
- 4. Antigen discovery and immunogen design
- 5. Pre-formulation work
- 6. In vitro studies
- 7. Early in vivo studies



- 8. Development of animal challenge model with antigen(s)
- 9. Analysis of immune response
- 10. Development of immunisation strategy
- 11. Lead candidate(s) identification
- Other (please specify):

# Next page

## [Routing = if 'Pre-clinical development in Q18, show next question, else, skip it]

You have selected 'Pre-clinical development'. The <u>UKVN Vaccine Development Map for Pre-Clinical Development</u> outlines the steps involved in this stage of development.

21. Please select all the step(s) that were conducted during the implementation of your UKVN-funded project.

## [tick-box question]

- 1. Lead candidate(s) identification
- 2. Production of Master Seed Bank (pre-GMP)
- 3. Lead candidate(s) development (analysis of immune correlates of protection)
- 4. Candidate optimisation: re-cloning, strain development and antigen presentation
- 5. Early process development (testing suitability of candidate for manufacturing)
- 6. Animal Studies In vitro studies
- 7. Animal Studies In vivo studies
- 8. Lead product(s) identified
- 9. Process development for scalable GMP manufacturing process; Tech transfer to GMP site
- 10. Reassessment of target product profile
- Other (please specify)
- 22. Further, in relation to process validation and clinical manufacture, please select all the step(s) that were conducted during the implementation of your UKVN-funded project.

#### [tick-box question]

- 11. Quality control and stability testing
- 12. Development of fill/finish process
- 13. Engineering batches to finalise process validation
- 14. Animal toxicity study (for clinical trial application data)
- 15. GMP manufacture (bulk)
- 16. GMP manufacture (fill/finish)
- 17. Preparation of clinical trial applications
- 18. Preparation for clinical development (technology transfer documents)
- Other (please specify):



# Next page

# [Routing = if 'Clinical development' in Q18, show next question, else, skip it]

You have selected 'Clinical development'. The <u>UKVN Vaccine Development Map for Clinical Development</u> outlines the steps involved in vaccine development at Phase I and Phase II stages.

23. Please select all the step(s) that were conducted at Phase I clinical development stage during the implementation of your UKVN-funded project.

#### [tick-box question]

- 1. Identification of lead product(s) for possible clinical development
- 2. Go/No go decision to enter clinical development (vaccine safety testing, pilot manufacturing, etc)
- 3. Review of target product profile
- 4. Clinical study design Phase I
- 5. Request/obtain ethical and regulatory approval Phase I
- 6. Implementation of Phase I clinical trial
- 7. Lead indication confirmed
- Other (please specify):
- 24. If relevant, please select all the step(s) that were conducted at Phase II clinical development stage during the implementation of your UKVN-funded project

#### [tick-box question]

- 8. Review of target product profile
- 9. Clinical study design Phase II
- 10. Request/obtain ethical and regulatory approval Phase II
- 11. Implementation of Phase II clinical trial
- 12. Seeking scientific advice from regulatory authorities and HTA bodies
- 13. Full clinical development decision (Go/No go decision)
- 14. Other activities: preparation of safety documents, regulatory and ethics engagement, manufacturing, final manufacturing process validation, commercial development, comparative immunogenicity assays.
- Other (please specify):

#### [Routing = Project lead Only]

25. If applicable, please provide the clinical trial registration number(s), references or links to the clinical trial(s) performed in your UKVN-funded project:

[comment box]

<<End of Vaccine R&D questions>>

# Next page



#### [Routing = ALL]

Research and development outputs

26. Which of the below option(s) best describe **the main output(s)** of your UKVN-funded project? Select all that apply:

#### [tick-box question]

- Developed / progressed a new vaccine candidate
- Developed / progressed a novel platform for vaccine development
- Developed / progressed diagnostics tools
- Developed / progressed new manufacturing techniques
- Developed / progressed protocols and processes for vaccine trialling
- Developed / progressed epidemiological models for optimal vaccine deployment
- Other (please specify):

#### [Routing = All]

#### [Routing 2 = Hide this question if answer to Q24 = 'None of the above']

27. Please provide a brief summary of the main project output(s), including references and weblinks.

#### [comment box]

#### [Routing = All]

Publication and knowledge dissemination outputs

#### [tick-box question]

- 28. Which of the following outputs has your UKVN-funded project produced to date? Select all that apply:
- Peer-reviewed scientific publications
- International conference presentation
- Tools, databases or sample collections
- National or international strategy and policy documents (including guidelines)
- Participation in formal working groups or high-level expert panels
- Training / public awareness material
- Other (please specify):
- None of the above

# [Routing = All]

# [Routing 2 = Hide this question if answer to Q28 = 'None of the above']

29. Please provide a brief summary of the knowledge dissemination outputs, including references and weblinks. If a list of publication is available (e.g. DOI), please provide it, as we will triangulate it with other sources.

#### [comment box]



#### [Routing = All]

Intellectual property and commercial outputs

- 30. Which of the following intellectual property (IP) and commercial outputs has your UKVN-funded project produced to date? Select all that apply:
- Patent application (pending)
- Patent granted
- Licensing agreement
- Spinout company created
- Other (please specify):
- None of the above

#### [Routing = AII]

#### [Routing 2 = Hide this question if answer to Q30 = 'None of the above]

31. Please provide a brief summary of the IP and commercial outputs, including references and weblinks.

[comment box]

# [Routing = All]

32. Please describe any additional or unintended outputs resulting from your UKVN-funded project.

[comment box]

# Next page

#### Project outcomes and impacts

In this section, we would like to explore the outcomes and impact of the project, that is longer-term benefits and improvements, which originate (perhaps in part) from your research funded by the UKVN 1.0 programme. This may be due to your subsequent work, or work of others, in the research community and beyond.

#### [Routing = ALL]

Scientific outcomes

33. Have you or others started follow-on / additional work based on your UKVN-funded project results, **beyond your UKVN-funded project end**?

## [single-choice question]

- Yes
- No, but I know that follow-on work will be conducted in the near future
- No, but the UKVN-funded project results could be exploited in the longer term
- No, it is unlikely that the UKVN-funded project results will be exploited in the future
- Don't know



## [Routing = only show this question if 'Yes' or if 'No, but I anticipate follow-on...' in Q33 above]

- 34. Please provide further details and references/weblinks for the follow-on work, including:
- a) the type of work conducted (e.g. development of vaccine candidate, platform or manufacturing process, improvement of infrastructure);
- b) who has conducted / is conducting the follow-on work;
- c) funding sources and amount of funding (if known), including funding awarded under the next phase of the UKVN 2.0 (2023/24 onwards).

[comment box]

#### [Routing = hide this question if 'Yes' or if 'No, but I anticipate follow-on...' or 'Don't' know in Q33]

35. Please explain the barrier(s) to progressing UKVN-funded project results with further R&D or technology development

[comment box]

Collaborations and capacity building

# [Routing = All]

[single-choice question]

- 36. Have your skills and capacity (and those of your colleagues <u>in your organisation</u>) increased as a result of collaborating with / training provided by project partners?
- Yes
- No

#### [Routing = if 'No' in previous question, skip/hide next question]

37. Please provide details about how the collaboration and/or training received has benefitted you and/or colleagues in your organisation. If known, please include the type of training activity (e.g., laboratory-based training, good manufacturing practices, data analysis, community engagement) and the estimated number of individuals benefiting from it.

[comment box]

#### [Routing = All]

38. Do you believe your UKVN-funded project has contributed to building a stronger R&D community overall that is ready and able to support future public health emergencies? Please explain briefly your response:

[comment box]

Health and societal outcomes

#### [Routing = ALL]

39. Have your UKVN-funded project results contributed to the following outcomes in low- and middle-income countries to date? Select all that apply:

#### [tick-box question]

- Protocols and processes for using / trialling vaccines are outbreak ready
- Licensed or unlicensed vaccines are ready for use / trialling when outbreak occurs



- New technologies accelerate vaccine response to an unknown pathogen
- Improved infrastructure and products to support emergency vaccine deployment
- Increased prevention and/or reduction of the likelihood of public health emergencies
- None of the above
- Other (please specify):

#### [Routing = All]

## [Routing 2 = Hide this question if answer to Q39 = 'None of the above']

40. Please provide details, references and/or weblinks to the outcomes indicated above.

[comment box]

#### [Routing = Only for Companies: SME or Large enterprises]

Commercial outcomes to companies

[tick-box question]

- 41. Has the UKVN-funded project led to commercial benefits for your organisation? Select all that apply:
- Yes, the project has led to IP protection and/or licensing deal
- Yes, the project has led to growth in turnover at my organisation
- Yes, the project has led to increased employment at my organisation
- No commercial benefits have emerged yet, but it has the potential to do so
- No, it is unlikely that commercial benefits will be realised in the future
- Not relevant for this UKVN-funded project
- Other (please specify):

#### [Routing = if any of the 'Yes', or 'Not yet', options above, show below question]

42. Please provide further details of commercial benefits achieved (if possible).

[comment box]

# Next page

[Routing = If Q5 = Two Projects, repeat ALL sections around project details i.e., project team, project experience and learnings, project outputs, project outcomes and impacts]

[Repeat project pages]

You have now completed the survey regarding your <u>first project</u>. Thank you very much for your support so far. The section below will ask you questions regarding your <u>second project.</u>

Please provide answers to the following questions <u>related to your second project</u> (may involve two linked grants) below.



# Next page

[Routing = for those with One project in Q5, go straight to below question, for others, first iterated as above]

Thank you for providing information about your project(s). We will now ask you a final question about the design and management of the funding programme.

# Design and management of the funding programme

# [Routing = Project leads only]

43. How satisfied were you with the following aspects of the funding programme? [Likert matrix question]

	Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied	Don't know
Scope of research competition(s) including funding levels and project length						
Research competition guidelines						
Feedback provided about the outcome of the proposal assessment						
Contracting timelines						
Interaction with project monitoring officers						
Project monitoring/reporting requirements and processes						
Other (please specify)						

Please leave any comments regarding your response above:

[comment box]

# [Project partners only]

44. How satisfied were you with the following aspects of the management of your project? [Likert matrix question]

	Very satisfied	Satisfied	Neutral	Dissatisfied	Very dissatisfied	Don't know / N/A
Communication of goals and objectives by the Project lead						
Management of project timelines and deadlines by the Project lead						
Support provided by the Project lead to complete my tasks						
Project lead's ability to resolve conflicts or address collaboration challenges						



Other (please specify)						
------------------------	--	--	--	--	--	--

Please leave any comments regarding your response above:

[comment box]

#### Closing

#### [Routing = All]

45. Do you have any further comments for the evaluators of the UKVN programme or suggestions to funders of future vaccine development programmes?

[comment box]

Please click 'Finish Survey' to submit your responses. You will not be able to return and modify your answers.

Thank you very much for your time and insights, these are extremely helpful to inform the evaluation. We will conduct interviews and develop case studies to showcase the different types of impacts and learnings of the UKVN programme, and thus we may contact you again if further details are requested.

# F.2 Wider stakeholders interview questions

The UKVN expert group was established in the context of the Ebola outbreak in West Africa in 2015. Its primary role is to advise the DHSC on R&D investment into vaccines, and function as a policy support hub. The UKVN 1.0 research programme represented UK government investment of £134m of Official Development Assistance (ODA) between 2016 and 2023 through delivery partners at the UK Research & Innovation and the National Institute for Health Research (NIHR). The aim of the UKVN 1.0 was to advance the development of vaccines and vaccine technologies that will benefit low- and middle-income countries (LMICs) and increase UK vaccines R&D capacity relevant to current and future health threats.

As part of this evaluation, we are consulting with UKVN-funded researchers and external stakeholders involved in vaccines R&D, including funders, academic experts, developers, decision makers in public health and others. Your participation in this interview will help us contextualise the UKVN's relevance and added value, alignment with priority areas and potential impact in LMICs.

## Consent/confidentiality

Before we start, may I request your permission for the following:

- We will report this information, such as data, opinions and views expressed, and any analysis we carry out as part of the evaluation in aggregate, and it will be published in a report. Where your contribution may be identifiable, we will ask for your explicit permission to include this information in the report. Do you agree to this?
- Can we include your name in a list of stakeholders consulted, which will be in an Appendix to the report?



• Can I have your permission to audio record the interview? The recording will only be used to ensure that we capture information correctly. It will not be provided to anyone outside the study team and it will be destroyed as soon as we have completed the evaluation.

Thank you, I have now started the recording.

#### **Background**

#### [All]

46. Can you tell me about your **current role** (and any relevant previous roles), and **experience** with vaccines R&D and relevant global health policy?

# [All]

47. To what extent are you **familiar with the UKVN programme**? Have you been involved in or interacted with UKVN working groups, or are you aware of any UKVN-funded projects?

#### Global health security and barriers to vaccines R&D

[All]

- 48. Back in 2016, overall, what were the **key issues for global health security in LMICs**? Are these issues still relevant?
  - Probe: emerging infectious diseases and epidemics (Ebola in West Africa, Zika in Latin America) without vaccine and/or treatment.
  - Weak health systems (availability of diagnostics, surveillance, work force).

## [All]

- 49. More specifically, what were the **barriers for developing vaccines for epidemic diseases**? Are these barriers still relevant today?
  - Probe: gaps in vaccines R&D funding landscape (e.g. insufficient/sustained funding);
     who funded vaccines R&D then and now?
  - Other barriers: lack of relevant R&D capacity, infrastructure, regulatory, IP, manufacturing and supply chain.

## Role of UKVN in the vaccines R&D funding landscape

[All]

- 50. In your view, to what extent the **UKVN programme fit into / fill a gap in the global vaccines R&D funding landscape**?
  - Did it address the right priorities? Did it align with LMICs needs? Ask for examples.



- Probe: targeted priority diseases<sup>38</sup> without vaccines/treatment that lacked commercial potential
- Focussed on early-stage vaccines development to bridge the funding gap from preclinical to clinical studies
- Included projects on novel vaccines platforms, epidemiological approaches, One health (animal vaccines), and manufacturing technologies to accelerate development of vaccines for clinical trials and deployment
- Included the right organisations: academic, commercial, research institutes, government agencies – in higher income countries and LMICs
- How significant and/or unique was the UKVN? Did it <u>provide 'added value' for vaccines</u> R&D and global health policy?

#### [Research funders or individuals based in the UK only]

51. In your view, as a result of UKVN funding, are **UK researchers better positioned** today to contribute to the global challenge of vaccine development for epidemic diseases?

#### The potential for (future) impact of UKVN in LMICs

#### [All]

- 52. Are you aware of any **specific outputs** from UKVN projects that contributed to new knowledge, tools, protocols, vaccines candidates, etc? If yes, please explain further.
  - Probe: Awareness of contribution of UKVN funding to the <u>development of the ChAdOx1</u> <u>platform</u>. To what extent the Oxford-AstraZeneca vaccine was significant to combat the COVID-19 pandemic in LMICs?
  - Probe: <u>multivalent vaccine candidates</u> for targeting multiple pathogens

#### [All]

53. Do you think the UKVN-funded research contributed to **capacity building**, in the UK and in LMICs?

If yes, ask for examples, if possible, scale and type of skills/knowledge improved (e.g. research skills, manufacturing technologies, epidemiology/social science, regulation/industry standards, international networks)

#### [All]

54. From what you have seen so far, do you think UKVN-funded projects has already contributed/will contribute to better preparedness and more rapid, effective response to future outbreaks in LMICs?

- Probe: UKVN contribution to "100 Days Mission" or viral family approaches (see CEPI)
- Probe: What else needs to happen so that the impacts are realised?

<sup>&</sup>lt;sup>38</sup> Chikungunya, Crimean-Congo Haemorrhagic Fever, Ebola, Hantavirus, Lassa, Marburg, Middle East Respiratory Syndrome, Nipah, Plague, Q Fever, Rift Valley Fever, Zika. In addition to these, the UKVN list included 'Disease X', referring to unknown pathogens which can cause epidemics.



- Promising candidates/technologies receive further investment from other funders; any remaining gaps in the funding landscape?
- Regulatory approval of safe/effective vaccines; any known generic regulatory hurdles?
- Country and political acceptance of vaccine deployment and capacity deliver;
   how can the UK and others support this aspect?
- Probe: How important was the UKVN-funded project to achieve this impact?
- 55. In hindsight, what could have increased the UKVN-funded projects' **potential to achieve maximum impact**?

#### **UKVN's Engagement & Policy leadership**

[All]

- 56. Are you aware of the tools developed by the UKVN expert groups, such as the **list of 12 priority pathogens**<sup>39</sup> for vaccine development in 2016 or the <u>Vaccine Development Process</u> <u>Map</u> (for human and veterinary vaccines)? If yes, do you think these were useful to the vaccines R&D community?
- 57. Do you know if UKVN experts or researchers funded by the UKVN contributed to **international policy discussions** at the WHO or in LMICs?

#### Final comments and close

- 58. Do you have any other comments about the UKVN programme or any suggestions to the UK funders?
- 59. [If applicable] Who else in your view we should talk to in relation to the impact of the UKVN on LMICs, and could you provide contact/introduce us?

Thank you very much for your time and insights; this is very helpful to inform the study. If there are any clarification questions or additional aspects to check with you, may I contact you again?

<sup>&</sup>lt;sup>39</sup> Chikungunya, Crimean-Congo Haemorrhagic Fever, Ebola, Hantavirus, Lassa, Marburg, Middle East Respiratory Syndrome, Nipah, Plague, Q Fever, Rift Valley Fever, Zika. In addition to these, the UKVN list included 'Disease X', referring to unknown pathogens which can cause epidemics.



# Appendix G UKVN 1.0 vaccine R&D projects and global investment

#### **UKVN 1.0 vaccine R&D projects**

The vaccine R&D project analysis includes 48 projects, supported by 64 awards. Each project tends to align with one vaccine candidate, may have received several linked or consecutive UKVN1.0 awards and have been led by the same team. However:

- Some vaccine candidates were developed for more than one use (e.g. veterinary/human), and/or by different groups. In this case, the candidates were 'double-counted' (eg projects led by different groups developing MVA-GP CCHFV for use in livestock and in humans)
- Some awards led to the development of more than one candidate (e.g. a project developing multivalent candidates against two species of Ebola virus, Marburg virus and Lassa virus led to additional UKVN 1.0 awards, for a bivalent and a monovalent candidate. This was recorded as two projects (one per candidate), as they received separate grants and target different diseases.
- Where a project targeted candidate(s) for multiple pathogens, it is included in all relevant disease sections, i.e. counted multiple times.
- A small number of projects (3) developed vaccine candidates for veterinary use. For these, the definition of 'clinical development' was adjusted: where applicable, a veterinary field trial was considered equivalent to a Phase I clinical trial.

Projects that did not target a specific candidate are analysed separately. In addition, it should be noted that many UKVN vaccine R&D projects contributed to progress beyond their targeted vaccine candidate, underpinning platform development, manufacturing, and vaccine development tools and data more broadly.

#### Global investment in vaccine R&D

Global investment in vaccine R&D for the twelve UKVN priority diseases was analysed using the G-FINDER database. All investment figures reported in this appendix were extracted from G-FINDER.<sup>40</sup>

G-FINDER aggregates R&D investment data combining a funder survey and analysis of publicly available funding data. Limitations to the data hence include survey non-completion, time lags in the funding process, an inability to disaggregate some investments, and non-comparable or missing data. The data can hence only be considered indicative.

For seven of the eight UKVN priority pathogens tracked by G-FINDER from 2016 to 2023, the UKVN portfolio shows higher funding levels than those reported for the UK by G-FINDER. For ZIKV, CCHF and RVF, the discrepancy is less than 20%; however, for EBOV, MARV, LASV, and NiV, the UK funding reported in G-FINDER is less than 30% of the amount set out in the UKVN vaccine R&D portfolio data. For MERS, G-FINDER reports a much higher funding amount for the UK compared to the UKVN data (75% higher).

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<sup>&</sup>lt;sup>40</sup> G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025



# G.1.1 Viruses causing haemorrhagic fevers: Ebola, Marburg, Lassa and CCHF viruses

R&D projects targeting Ebola, Marburg and Lassa virus

The UKVN supported eight vaccine R&D projects targeting EBOV, SUDV, MARV and LASV, in different combinations with each other and with other targets (Table 18). Six of the eight projects targeted more than one pathogen. The projects received a total of £11.6 million, representing 16% of UKVN vaccine R&D funding. A further project delivered Phase IV trials on the persistence of immunity after vaccination with an approved EBOV vaccine, and the impact of a booster dose.

By pathogen, £5.4 million (7.5% of UKVN vaccine R&D funding) was allocated to EBOV/SUDV; £3.3 million (4.6%) to MARV, and £2.9 million (4.0%) to LASV. Altogether, projects focussed on the filoviruses - EBOV, SUDV and MARV - received £8.7 million, making up 12% of the total portfolio.

Table 18 UKVN 1.0 vaccine R&D projects targeting viral haemorrhagic fevers

Vaccine platform category	Target	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end date
Viral	(EBOV, SUDV, MARV, LASV)	(ChAdOx/MVA multivalent)	971510/971615/10025997: Clinical trial assessment of a multivalent vaccine against
vector	EBOV, SUDV	ChAdOx1 biEBOV (U of Oxford)	Ebola virus (2017-2018, 2018-2022, 2022-2023)
Viral vector	MARV	ChAdOx1-MARV (U of Oxford)	10025020: GMP Manufacture of a vaccine targeting a viral haemorrhagic fever (2022-2023)
Viral vector	Filoviruses - EBOV, MARV	FILOcepX (U of Oxford)	971522: Pan-filovirus T-cell Vaccine Designed as Bi-valent Conserved Region Epigraphs (2017-2018)
Viral vector	EBOV, MARV, LASV	HFVac3 (U of Cambridge)	971511/971616: Clinical trial of a DIOS Trivalent Haemorrhagic Fever Vaccine (DIOS-HFVac3) (2017-2018, 2018-2023)
Viral vector	EBOV, MARV, LASV, CCHF	HFVac4 (Diosynvax Ltd)	10026830: HFVac4: A Quadrivalent Viral Haemorrhagic Fever Vaccine for Africa (2022- 2024)
Viral vector	LASV	MVA-LassaVacc (PHE/UKHSA)	972223: LassaVacc (2016-2017)
RNA	EBOV, MARV, LASV	EML-VAC (Imperial College London)	971507/971617: EML-VAC: Multivalent replicon vaccine against Ebola, Marburg and Lassa viruses (2017-2018; 2018-2022)
RNA	EBOV, CHIKV, ZIKV	(Activirosomes Ltd)	971524: Preclinical PoC of multivalent vaccine agents & technology platform
Viral vector	EBOV, SUDV	Post-vaccination (U of Oxford)	971553: Ebola vaccines: persistence of immunity & response to booster dose of MVA-EBO Z (2017-2022)

Source: Survey and final project reports.

Around £1 billion in global R&D funding was invested in vaccine R&D targeting EBOV and SUDV between 2016 and 2023. Approximately two thirds of funding were from public and philanthropic funders (£650m), and one third from industry (£387m, 37%). Annual funding levels



were highest in 2016, at £266 million (£136m from public funders), and have declined steadily since, reaching £35 million in 2023 (£26m from public funders). Most public funding was provided by US agencies (80%, £502m), mainly BARDA, NIH, and DoD, and the European Union (19%, £117m). UK public funders contributed less than 1% (£1.8m, Innovate UK, DHSC), with the Wellcome Trust providing £11 million in funding.

Vaccine R&D targeting MARV saw around £161 million in investment between 2016 and 2023. Annual funding levels were below £5 million in 2016 and 2017, rose to £20 million in 2018 and have increased steadily since, to £31 million in 2023. Nearly all funding was from public sources in the USA (98%), mainly the US DoD, BARDA and NIH. The UK contributed less than 1% (£0.5m, Innovate UK).

Vaccine R&D targeting LASV and LASV in combination with related viruses was supported with around £42 million in between 2016 and 2023, stemming almost exclusively from public funders (£41m, 98%). No clear funding trends are identifiable; funding was lowest in 2016 (£1.4m) and highest in 2022 (£8.7m). Most of the funding was provided by US agencies (97%, £40m), notably the NIH and DoD. UK public funders contributed less than 2% of funding (£0.7m; Innovate UK, DHSC), with an additional £0.6 million from the Wellcome Trust.

#### R&D projects targeting Crimean-Congo Haemorrhagic Fever virus

The UKVN 1.0 funded six vaccine R&D projects targeting Crimean-Congo Haemorrhagic Fever virus (CCHFV), with one project focussed on a multivalent candidate (CCHFV, EBOZ, MARV, LASV) (Table 19). Three projects progressed the same vaccine candidate, MVA-GP CCHF, for different uses (livestock / human) and to facilitate its deployment in low-resource settings (room-temperature stable, ready-to-inject formulation). In total, the UKVN allocated £9.3 million to the portfolio, representing 12.9% of its vaccine R&D funding for all 12 priority pathogens.

Table 19 UKVN 1.0 vaccine R&D projects targeting CCHFV

Vaccine platform categor y	Target	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end dates
Viral vector	CCHFV	MVA-GP (PHE/UKHSA)	972213: Phase I Study of a Modified Vaccinia Ankara (MVA) based vaccine for Crimean Congo Haemorrhagic fever (2016-2024)
Viral vector	CCHFV	MVA-GP (Pirbright Inst)	16/107/06: Advanced development of a safe and effective CCHF vaccine for livestock and humans (2016-2021)
Viral vector	CCHFV, EBOZ, MARV, LASV	HFVac4 (Diosynvax)	10026830: HFVac4: A Quadrivalent Viral Haemorrhagic Fever Vaccine for Africa (2022-2024)
Viral vector	CCHFV	ChAdOx2- CCHF (U of Oxford)	971519/971614: CCHF Vaccine manufacturing and First in Human Clinical Trial (2017-2018, 2018-2022)
Protein- based subunit	CCHFV	Expression in insect cells (OET)	972227/972237/10025531: Development of a subunit vaccine against CCHF virus for use in LMICs; completion of preclinical studies (2016-2017, 2018-2022, 2022-2023)
mRNA	CCHFV	PTX-V6 (Phion Therapeutics)	10026224: A Peptide-mRNA Vaccine for Crimean-Congo Haemorrhagic Fever (CCHF) (2022-2023)

Source: Survey and final project reports.



Global investment in CCHF vaccine R&D totalled approximately £24 million between 2016 and 2023<sup>41</sup>. Annual funding levels fluctuated year-on-year, with a low of £0.8 million in 2016 and a high of £4.9 million in 2022. Most funding was provided by public funders (96%, £23m). Funders in the US and UK provided around one third each (approx. £8m, for UK from Innovate UK and DHSC), with the European Union accounting for 26% (£6.0m).

# G.1.2 Mosquito-borne arboviruses: Chikungunya, Zika and Rift Valley fever viruses

R&D projects targeting chikungunya virus (CHIKV)

The UKVN 1.0 supported eight vaccine R&D projects targeting CHIKV (Table 20), allocating £9.1 million in total (12.6% of the portfolio). Five of the eight projects targeted other pathogens alongside CHIKV or were more broadly protective (e.g. immune response to mosquito bites).

Table 20 UKVN1.0 vaccine R&D projects targeting CHIKV

Vaccine platform category	Target	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end dates
Viral vector	CHIKV	MV-CHIK (Themis Bio, AT)	971574: Identification & Validation of Correlate of Protection for a Chikungunya Vaccine (2017-2021)
Viral vector	CHIKV	ChAdOx1 CHIK (U of Oxford)	972212: A phase I clinical trial of a Chikungunya vaccine using a single dose and no adjuvant (2016-2019)
Viral vector	CHIKV, ZIKV	ChAdOx1 ZIK/CHIK (U of Surrey/Oxford)	971557/10025262: A simple, multivalent vaccine to prevent Zika and Chikungunya: progression and readiness to phase II trial (2017-2022, 2022-2024)
Protein- based subunit	Mosquito- borne	AGS-v PLUS (Imutex/ConserVBi o)	971556: Vaccine against mosquito-borne diseases (2017-2021)
Particle- based subunit	CHIKV, RVFV	(Leaf Systems Int.)	971513: Development of Virus-Like Particles as vaccines against emerging viral diseases (2017-2018)
Synthetic peptide subunit	CHIKV	CD8 T-Cell priming (Emergex/Gylden)	10025629: Development of a CD8 T-Cell Priming Vaccine Against Chikungunya Virus (2022-2023)
mRNA	CHIKV, ZIKV, EBOV	(Activirosomes Ltd)	971524: Preclinical PoC of multivalent vaccine agents & technology platform (2017-2018)
mRNA	CHIKV	AV-CHIK-321 (Activirosomes Ltd)	10026738: Preclinical characterization of a novel vaccine for prevention of Chikungunya (2022-2023)

Source: Survey and final project reports.

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<sup>&</sup>lt;sup>41</sup> G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025



According to G-FINDER, around £109 million in global R&D funding was invested in CHIKV vaccine R&D between 2018 and 2023<sup>42</sup>. After an initial peak of £16 million invested in 2019, funding levels dropped to £7.5 million in 2021, before rising again sharply to £51 million in 2023.

From 2018 to 2020, almost all funding was from public sector sources (£37m), but since 2021, industry funding has increased to match public sources, likely reflecting the progress of Valneva's and Bavarian Nordic's candidates towards licensure. From 2021 to 2023, industry provided £38 million in funding.

Public funding totalled £69 million from 2018 to 2023, mainly from the European Union (£36m, 51%) and the USA (£25m, 36%, from US NIH). The UK contributed 8% (£5.3m, Innovate UK).

# R&D projects targeting Zika virus (ZIKV)

The UKVN 1.0 supported fourteen vaccine development projects targeting ZIKV (Table 21), with £19.0 million in funding, representing a 26.3% share of the UKVN vaccine R&D portfolio.

The portfolio included six projects targeting more than one pathogen, or more broadly protective vaccine candidates, e.g. triggering immune responses to mosquito bites.

Table 21 UKVN 1.0 vaccine R&D projects targeting ZIKV

Vaccine platform category	Target	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end dates
Viral vector	ZIKV	ChAdOx-ZIKV (U of Oxford)	972216: Protective efficacy and neutralisation to select an optimal Zika virus vaccine (2016-2017) 16/107/05: Design, development, GMP manufacture and Phase I trials of a Zika vaccine (2016-2022) (also below)
Viral vector	ZIKV, CHIKV	ChAdOx1 ZIKV and ZIKV/CHIK (U Oxford/ U Surrey)	971557/10025262: A simple, multivalent vaccine to prevent Zika and Chikungunya: progression and readiness to phase II trial (2017-2022, 2022-2024)
Viral vector	ZIKV	MVAZIKAB (U of Liverpool)	971554: A phase I study of recombinant poxvirus Zika vaccines (2017-2022)
Viral vector	ZIKV	MV-ZIKA (Themis, AT)	972215: Development of a single dose ambient temperature stable vaccine for the prevention of Zika virus (2016-2018)
Viral vector	ZIKV	(IosBio Ltd)	972219/972236: An Oral Zika Vaccine (2016-2017, 2018-2021)
Protein- based subunit	ZIKV, DENV	Zika-HX (Excivion Ltd)	972224/972238: Clinical Development of a Zika Vaccine Avoiding Disease Enhancement (2016-2017, 2018-2020)
Protein- based subunit	Flaviviruse s	Fc fusion vaccines (Liverpool School of Tropical Medicine)	971526: Adjuvant-free vaccines and companion diagnostics to control emerging flaviviruses (2017-2018)

<sup>&</sup>lt;sup>42</sup> 2018 is the first year for which data is available. G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025. Four of eight UKVN 1.0 projects targeting CHIKV were allocated before 2018; we hence were not able to determine the UKVN's share of global funding.



Protein- based subunit	Mosquito- borne	AGS-v PLUS (Imutex/ConserV)	971556: Vaccine against mosquito-borne diseases (2017-2021)	
Particle- based subunit	ZIKV	VLP (U of Glasgow)	16/107/05: Design, development, GMP manufacture and Phase I trials of a Zika vaccine (2016-2022) [also ChAdOx1 ZIKV, see above]	
Particle- based subunit	ZIKV	Nanoparticle-based (Vaxinano, FR)	971517: Nanoparticle-based Vaccine Platform against Zika Virus Infection (2017-2018)	
Synthetic peptide subunit	ZIKV/filovir us	Synthetic GNP (Emergex/Gylden)	971512: Validation and cGMP manufacture of a Ziko and Multivalent Filovirus vaccine (2017-2018)	
DNA	ZIKV	Zika NS1 (U of Nottingham)	10026208: A Single-dose DNA vaccine platform to safely induce protective immunity against Zika (2022-2023)	
mRNA	ZIKV, CHIKV, EBOZ	Activirosomes Ltd	971524: Preclinical PoC of multivalent vaccine agents & technology platform (focused on vaccines for Chikungunya, Zika, and Ebola) (2017-2018)	
Other	ZIKV	Oral vaccine (Vaxonella/Prokariu m Ltd)	972222: An affordable, oral vaccine against mosquito- and sexually-transmitted Zika virus (2016-2017)	

Source: Survey and final project reports.

According to G-FINDER, approximately £458 million in global R&D funding was invested in ZIKV vaccine R&D between 2016 and 2023<sup>43</sup>. Annual funding levels were highest from 2016 to 2018, at £94-131 million, dropped sharply in 2019 to £35 million, and declined steadily in the following years, reaching £19 million in 2023 - likely reflecting the decreasing Zika case numbers.

The majority of funding was provided by public funders (87%, £397m), followed by industry (13%, £16m). Public funders in the USA provided the largest amount of funding (90%, £358m; mainly US BARDA and US NIH), followed by public funders in the UK (4.6%, £18m, Innovate UK and DHSC).

#### R&D projects targeting Rift Valley Fever virus (RVFV)

The UKVN 1.0 supported five RVFV vaccine R&D projects (Table 22), including two projects targeting multiple pathogens (RVFV/CHIKV; RVFV/Q Fever). In total, the UKVN allocated £4.7 million to the portfolio, representing 6.5% of UKVN vaccine R&D funding.

Table 22 UKVN 1.0 vaccine R&D projects targeting RVFV

Vaccine platform category	Target Vaccine candidate Project grant reference(s), titles an		Project grant reference(s), titles and start-end dates
Viral vector	RVFV	ChAdOx1 RVF (U of Oxford/MRC Uganda Virus Research Inst)	16/107/02: Phase I studies of a novel chimpanzee adenovirus Rift Valley Fever vaccine for humans (2016-2021)

<sup>&</sup>lt;sup>43</sup> G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025



Viral vector	RVFV (livestock)	ChAdOx1 RVF (Pirbright/U of Oxford)	16/107/03: Advanced development of a safe and effective Rift Valley Fever vaccine for livestock (2016-2021)	
Viral vector	RVFV, Q Fever	BoHV-4 (Plymouth University)	971514: Multivalent Attenuated Vaccine against Viral and Bacterial Zoonoses in Ruminants (2017-2018)	
Inactivate d/Live- attenuate d	RVFV	Xvacc (UKHSA/PHE)	971508: Exploitation of x-ray irradiated viruses for vaccine development (2017-2018)	
Particle- based subunit	RVFV, CHIKV	Leaf Systems Int	971513: Development of Virus-Like Particles as vaccines against emerging viral diseases (2017-2018)	

Source: Survey and final project reports.

According to G-FINDER, around £39 million in global R&D funding was invested in RVFV vaccine R&D between 2016 and 2023<sup>44</sup>. Annual funding levels were below £2 million from 2016 to 2018, increased to £9.1 million in 2019, and reached a peak in 2022 (£18m). All funding came from public sources, mainly the European Union (£31m, via CEPI), with the UK and the USA contributing approx. 11% each (£4.4m; DHSC, Innovate UK).

G.1.3 Respiratory and rodent-borne viruses: MERS-CoV, Nipah virus, and Hantavirus

R&D projects targeting Middle East Respiratory Syndrome (MERS)

The UKVN 1.0 funded three vaccine R&D projects targeting MERS-CoV (Table 23), including one project developing a pan-coronavirus vaccine (pan-viral family approach) and one project targeting development of two vaccines using the same formulation technology (MERS, plague). In total, the UKVN allocated £2.5 million to the portfolio, representing 3.5% of UKVN vaccine R&D funding.

Table 23 UKVN 1.0 vaccine R&D projects targeting MERS-CoV

Vaccine platform category	Target	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end dates
Viral vector	MERS-CoV	ChAdOx1 MERS (University of Oxford)	16/107/01: Phase I studies of a novel chimpanzee adenovirus MERS vaccine (2016-2021)
Protein-based subunit	MERS- CoV, plague	Vaxcine/CaP-PCMC (Proxima Concepts Ltd)	972228: Self-administered vaccines directed against Plague and MERS (2016-2017)
mRNA	pan- coronavir us	UNICOR-v (ConserV Bio Ltd)	10025510: Pan-coronavirus vaccine (2022- 2023)

Source: Survey and final project reports.

<sup>&</sup>lt;sup>44</sup> G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025



According to G-FINDER, around £49 million in global R&D funding was invested in MERS-CoV vaccine R&D between 2016 and 2023<sup>45</sup>. Annual funding levels rose steadily from £6.7 million in 2016 to £9.9 million in 2020, and then dropped to lower levels during and after the COVID-19 pandemic. Most of the funding came from public funders (75%) and philanthropic organisations (24%). The USA contributed the largest amount (US NIH, £30m, 62%), followed by South Korea (£14m, 28%, almost all from the Samsung Foundation). South Korea's focus on MERS stems from the 2015 MERS outbreak in the country, which resulted in 38 deaths and the quarantine of 17,000 individuals<sup>46</sup>. The UK contributed 9% of funding (£4.4m; DHSC; Innovate UK).

#### R&D projects targeting Nipah Virus (NiV)

The UKVN 1.0 funded three vaccine R&D project targeting NiV (Table 24), providing a combined total of £3.0 million. This represents 4.1% of UKVN vaccine R&D funding.

Table 24 UKVN 1.0 vaccine R&D projects targeting NiV

Vaccine platform category Vaccine candidate (Lead organisation)		Project grant reference(s), titles and start-end dates
Viral vector	SeV NiV (Agri-Food and Biosciences Inst)	971523: Development of a novel Nipah Virus pre- fusion protein recombinant vaccine (2017-2018)
Viral vector	NiV PrV (Pirbright Institute)	971555, 10024897: A live attenuated pseudorabies virus vectored Nipah vaccine for enhanced protection in pigs (2017-2022, 2022-2023)
Viral vector	OraPro-Nipah (losbio/Stabilitech Ltd)	10027019: Oral Nipah Vaccine (2022-2023)

Source: Survey and final project reports

According to G-FINDER, global investment in NiV vaccine R&D totalled approximately £22 million between 2016 and 2023<sup>47</sup>. From 2016 to 2018, annual funding levels were below £2 million, rising to £2-3.5 million from 2019 to 2021, and reaching a peak in 2022 (£7.1m). Nearly all funding came from public funders (£20m), mainly the US NIH (£19m), with the UK contributing 4% (£0.8m, Innovate UK).

#### R&D projects targeting Hantavirus

The UKVN funded one project targeting Hantavirus vaccines (Table 25), providing a total of £2.5 million (3.4% of UKVN vaccine R&D funding).

<sup>&</sup>lt;sup>45</sup> G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025

<sup>&</sup>lt;sup>46</sup> Oh MD, Park WB, Park SW, et al. Middle East respiratory syndrome: what we learned from the 2015 outbreak in the Republic of Korea. Korean J Intern Med. 2018;33(2):233-246. doi:10.3904/kjim.2018.031

<sup>&</sup>lt;sup>47</sup> G-FINDER, <a href="https://gfinderdata.policycuresresearch.org/">https://gfinderdata.policycuresresearch.org/</a> Accessed 22 May 2025



Table 25 UKVN 1.0 vaccine R&D projects targeting Hantavirus

Vaccine platform category	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end dates
Viral vector	MVA SEO-HTN / HantaVacc (UKHSA/PHE)	971521/971618: Advancement of a cost-effective MVA-based Hantavirus vaccine (HantaVacc) (2017-2018, 2018-2022)

Source: Survey and final project reports.

# G.1.4 Bacterial pathogens: Yersinia pestis (plague) and Coxiella burnetii (Q fever)

#### R&D projects targeting Yersinia pestis (plague)

The UKVN 1.0 funded four plague vaccine R&D projects (Table 26), providing a total of £5.7 million. This represents an 8.0% share of the UKVN vaccines R&D portfolio. One project targeted two pathogens, Y. pestis and MERS-CoV.

Table 26 UKVN 1.0 vaccine R&D projects targeting plague

Vaccine platform category	Target	Vaccine candidate (Lead organisation)	Project grant reference(s), titles and start-end dates
Viral vector	Plague	ChAdOx PlaVac (U of Oxford)	972229/971558/10026240: Clinical development of the new ChAdOx1 Plague vaccine: A Phase 1b trial in a target population (2016-2017, 2017-2023, 2022-2024)
Protein- based subunit	Plague MERS	Vaxcine/CaP-PCMC (Proxima Concepts)	972228: Self-administered vaccines directed against Plague and Middle East Respiratory Syndrome (MERS) (2016-2017)
Other: recombina nt OMV- based	Plague	Outer Membrane Vesicles (OMV) (U of Norwich)	971525: Using engineered gut bacteria-derived microvesicles for Plague vaccines (2017-2018)
Other: live- attenuated bacterial vector	Plague	Vaxonella (Prokarium)	972211: Rapid, simple manufacture and clinical evaluation of an oral plague vaccine (2016-2019)

Source: Survey and final project reports.

# R&D projects targeting Coxiella burnetii (Q Fever)

The UKVN 1.0 funded three vaccine R&D projects targeting Q fever (Table 27), with one project focussing on a vaccine candidate for veterinary use and one project developing a multivalent vaccine against Q fever and RVF. The portfolio was supported with £4.2 million in funding, a 5.8% share of the UKVN vaccine R&D investment.

Table 27 UKVN 1.0 vaccine R&D projects targeting Q fever

Vaccine platform category	Target	Vaccine candidate (Lead organisation)		
Viral vector Q fever, RVFV BoHV-4 (U of Plymouth)		BoHV-4 (U of Plymouth)	971514: Multivalent Attenuated Vaccine against Viral and Bacterial Zoonoses in Ruminants (2017-2018)	



Viral vector / Other	Q fever	ChAdOx2 / LPS- based glycoconjugate (U of Oxford)	971515/971619: Development of a novel vaccine to protect against Q fever epidemics: late stage preclinical formulation and progression to clinical trial (2017-2018, 2018-2023)	
Particle- based subunit  Q fever VLP-based approach (Mologic Ltd)			972218/972239: Improved Q Fever Vaccine (2016-2017; 2018-2022)	

Source: Survey final project reports.

# G.1.5 Disease X / R&D targeting development of rapidly vaccine platforms

In addition to the vaccine R&D projects, the UKVN 1.0 portfolio funded eleven projects that specifically focussed on early-stage development and optimisation of novel vaccine platforms and delivery technologies with £5.5 million (Table 28).

Table 28 UKVN 1.0 projects: Platform development, formulation, and manufacturing

Project grant reference(s) and title	Lead organisation
971516: A novel livestock vaccination platform to prevent zoonotic emerging infections	University of Edinburgh
971518: Development of inducible expression-inactivated Leishmania as a vaccine carrier	Genefirst Ltd
971520: New Application of a DNA-nanorod Platform for Vaccine Development	U of Strathclyde
972220: A Conditional System for Inexpensive Manufacture of Attenuated Vaccines	Plymouth U
972221: Polyhedrin-encased glycoproteins as novel cold chain independent vaccines	Cell Guidance systems Ltd
972225: Room temperature stable Modified Vaccinia Ankara (MVA)-glycoprotein pox vectored vaccine against CCHF	Nova Biopharma Technologies Ltd
972226: Emerging Viral Vaccine Antigen Insert Consortium (EVAC)	U of Cambridge
972230: 'Plug and Display' Virus-like Particle Platform for Rapid Response Vaccination	U of Oxford
10026414: Delivering stabilised mRNA to cells for antigen production	John Innes Centre
10026700: The Protein Forge	The Protein Forge Ltd
16/107/04: A platform for the rapid development and production of candidate vaccines, analytical and diagnostic standards by plant-based transient expression for response to global viral threats (NIHR NETSCC)	John Innes Centre

Source: Survey and final project reports.



# G.1.6 Development of scalable manufacturing processes

The UKVN 1.0 funded two EPSRC Vaccine Manufacturing Research hubs with a total of £24.6 million<sup>48,49</sup>, and three projects that specifically focussed on manufacturing processes and infrastructure with a total of £1.5 million (Table 29).

Table 29 UKVN 1.0 projects: Manufacturing process and infrastructure development

Project grant reference(s) and title	Lead organisation
EP/R013764/1: Future Vaccine Manufacturing Hub	Imperial College London
EP/R013756/1: Vax Hub UCL & Oxford	University College London
10026212: Novel T cell-based vaccine potency assay to accelerate and improve development and manufacturing	Oxford Vacmedix UK Ltd
10025959: Rapid, accessible, globally distributed RNA vaccine manufacture on demand	Biologic Technologies Ltd
10026859: Manufacturing saRNA success	Imperial College London

Source: Survey and final project reports.

<sup>&</sup>lt;sup>48</sup> DoH/EPSRC Future Vaccine Manufacturing Research Hub, Call for proposals (Jan 2017); Amendment to Memorandum of Understanding between DoH and EPSRC, 5 March 2018

<sup>49</sup> https://devtracker.fcdo.gov.uk/programme/GB-GOV-10-UKVN-FVMRH-EPSRC/summary. Accessed 24 Feb 2025



# Appendix H Rapid Evidence Review

#### Developments in vaccine R&D and policy

#### H.1 Characteristics of vaccine R&D, commercialisation and access

Vaccine R&D has historically been characterised by long development timelines, high failure rates and high development costs.

Prior to 2020, the average vaccine development timeline from conception to regulatory approval was estimated at 10 to 15 years, with the Mumps vaccine holding the previous record at four years.<sup>50</sup> Another estimate for the average timeline from Phase I clinical trial to approval was around ten years.<sup>51</sup>

The failure rate of vaccine candidates is substantial. An analysis of 606 viral vaccine candidates for 23 viral infectious diseases, including ten of the twelve UKVN priority diseases, found wide variation in timelines, development activities, and success rates.<sup>52</sup> The study concluded that for the 2005-2020 time period, the probability of vaccines progressing from phase 2 to licensure within 10 years was 1 in 10 (10%). However, when influenza vaccines were excluded from the analysis (as they largely build on an established vaccine development platform), this number decreased to 1 in 30 (3.3%).

Vaccine development requires large R&D budgets, often coupled with low commercial incentives. A 2018 estimate of the cost of developing a vaccine from preclinical trials through to the end of phase 2a was between US\$319m and US\$469m (with a wide range from US\$137m to US\$1.1b), accounting for probability of success.<sup>53</sup> Another estimate of vaccine development costs ranged from US\$200m to US \$500m.<sup>54</sup>

Vaccine development for emerging infectious diseases faces a particular challenge due to the unpredictability of epidemics. In the absence of an outbreak, clinical trials may be paused or proceed at a slower pace due to a lack of immediate urgency and difficulty in recruiting participants.<sup>55</sup> The lack of outbreak data to demonstrate efficacy and safety in the target population can also make obtaining regulatory approval more difficult.

A recent example illustrates the uncertainty of clinical research on Emerging Infectious Diseases (EIDs). Vaccines currently approved for Ebola virus disease have only been evaluated against the Zaire strain, but other strains with outbreak potential exist. In September 2022, Uganda declared its first outbreak of Ebolavirus disease in a decade, caused by the Sudan Ebolavirus strain. Within two months, the World Health Organization (WHO) had coordinated a research plan to evaluate three viral vector-based candidate vaccines in a single Phase II trial (the

<sup>50</sup> Stuart LM. (2021) In Gratitude for mRNA Vaccines. N Engl J Med. 385(15) https://doi.org/10.1056/NEJMcibr2111445

<sup>&</sup>lt;sup>51</sup> Saleh A, et al (2021) Vaccine Development Throughout History. Cureus. 13(7):e16635. https://doi.org/10.7759/cureus.16635

<sup>&</sup>lt;sup>52</sup> MacPherson A *et al* (2020) Probability of Success and Timelines for the Development of Vaccines for Emerging and Reemerged Viral Infectious Diseases. *Ann Intern Med*. 174(3). <a href="https://doi.org/10.7326%2FM20-5350">https://doi.org/10.7326%2FM20-5350</a>

<sup>53</sup> Gouglas et al (2018) Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study. The Lancet Global Health. 6(12). <a href="https://doi.org/10.1016/S2214-109X(18)30346-2">https://doi.org/10.1016/S2214-109X(18)30346-2</a> 4

<sup>&</sup>lt;sup>54</sup> Plotkin et al (2017) The complexity and cost of vaccine manufacturing – An overview. Vaccine. 35(33). https://doi.org/10.1016/j.vaccine.2017.06.003

<sup>55</sup> Rezza, G & Weaver, SG (2019) Chikungunya as a paradigm for emerging viral diseases: Evaluating disease impact and hurdles to vaccine development. PLOS NTD. https://doi.org/10.1371/journal.pntd.0006919

<sup>&</sup>lt;sup>56</sup> Samarasekera U (2023) Solidarity Against Ebola: an update. The Lancet. Microbe 4(3):e139. https://doi.org/10.1016/s2666-5247(23)00035-6



Solidarity/Tokomeza Ebola trial). However, in January 2023, Uganda declared that its control measures had been successful and that it was Ebola outbreak free. Despite several thousand doses of candidate vaccines having already arrived in the country, the Tokomeza Ebola trial was no longer possible.

Regulatory approval can be further delayed by slower processes at national regulatory authorities in any low- and middle-income country (LMIC), e.g. due to limited capability and resources, less established regulatory frameworks, and logistical and bureaucratic challenges.<sup>57</sup> Pre-COVID-19 pandemic, the typical lag between the first regulatory submission, usually to a regulatory agency in a high-income country (HIC), and the final approval in Sub-Saharan Africa was between four and seven years.<sup>58</sup> A 2023 study found that the median time from vaccine ideation to first approval of the vaccine by a national regulatory authority in LMIC was 14.2 years.<sup>59</sup> As of November 2023, regulatory authorities of only twelve Upper Middle-Income Countries and four Lower-Middle-Income Countries were considered by WHO to have reached a sufficient maturity level.<sup>60</sup>

During the COVID-19 pandemic, the innovation timeline from conception to market was much accelerated. The first COVID vaccine was available after only 11 months (see section H.2), and government recommendations for use once vaccines were approved were instantaneous. Going forward, progress in vaccine platform development and manufacturing, as well as policy changes during the COVID-19 pandemic can be expected to reduce vaccine development timelines and costs.

#### H.2 Recent progress in vaccine technologies

Historically, vaccines used inactivated or live attenuated pathogens, which do not elicit disease symptoms but are able to generate an immune response.<sup>62</sup> Production processes for these vaccines need to be tailored specifically to each pathogen, and depending on the disease may require biosafety level 3 manufacturing.<sup>63</sup> This can hinder technology transfer to enable increased global manufacturing capacity.

In recent years, new types of vaccines have emerged. These vaccine platforms are based on viral vectors, RNA, or DNA, which instruct the vaccinated person's cells to produce a protein that triggers an immune response. Compared to previous approaches, the novel platforms can be quickly adapted to emerging diseases and confer advantages regarding the safety, scalability and reproducibility of vaccine manufacture, processing and storage.

<sup>&</sup>lt;sup>57</sup> O'Brien, J *et al* (2020) Building a Better Approach for the Benefit of Patients: 10 Pillars to Strengthen Regulatory Review Systems Globally. Ther Innov Regul Sci (54) 283–292 https://doi.org/10.1007/s43441-019-00055-9

<sup>58</sup> Ahonkhai V et al (2016) Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization. PLoS ONE, 11.
https://doi.org/10.1371/journal.pone.0166515

<sup>59</sup> Mao W, et al (2023) Comparing research and development, launch, and scale up timelines of 18 vaccines: lessons learnt from COVID-19 and implications for other infectious diseases. BMJ Glob Health 8.
https://doi.org/10.1136/bmjgh-2023-012855

World Health Organisation (2023) WHO Global Vaccine Market Report 2023. Available at: https://www.who.int/publications/i/item/B09022 Accessed 16 July 2024

<sup>&</sup>lt;sup>61</sup> Oliver SE et al (2021) The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine - United States, December 2020. MMWR Morb Mortal Wkly Rep. 69(5152). <a href="https://doi.org/10.15585/mmwr.mm695152e1">https://doi.org/10.15585/mmwr.mm695152e1</a>

<sup>&</sup>lt;sup>62</sup> Ghattas M et al (2021) Vaccine Technologies and Platforms for Infectious Diseases: Current Progress, Challenges, and Opportunities. Vaccines 9(12):1490. <a href="https://doi.org/10.3390/vaccines9121490">https://doi.org/10.3390/vaccines9121490</a>

<sup>&</sup>lt;sup>63</sup> Excler JL et al (2021) Vaccine development for emerging infectious diseases. Nat Med 27, 591–600 https://doi.org/10.1038/s41591-021-01301-0



The first vaccine based on one of these novel approaches was approved in late 2019 - the viral vector-based ERVEBO® against the Ebola virus.<sup>64</sup> The arsenal of technologies expanded during the COVID-19 pandemic, when the use of a variety of novel platforms contributed to the development and regulatory approval of vaccines in unprecedented timeframes. Previously, the average timeline from clinical trial to approval had been around ten years, while approval and rollout of COVID-19 vaccines based on RNA and viral vector platforms began within twelve months.<sup>65,66</sup> First approval of the vaccine by an LMIC national regulatory authority, with a previous median of 14.2 years from ideation, took only 0.92 years for COVID-19 vaccines.<sup>67</sup>

To date, at least ten new viral vector vaccines and four mRNA vaccines have been approved, including the viral vector vaccine ChAdOx1-nCoV-19, developed by the University of Oxford and AstraZeneca, and most recently, Moderna's mRNA vaccine against respiratory syncytial virus (RSV), which was approved in May 2024.68.69 A vaccine candidate against Chikungunya using virus-like particles (molecules that resemble viruses but lack infectivity because of the absence of viral genetic material) was submitted in the United States (US) and the European Union (EU) for regulatory approval in June 2024.70 As of December 2023, 249 active company-sponsored vaccine candidates against 31 infectious diseases were in clinical development. Approximately 37% of these were based on novel vaccine technologies, e.g. 53 were RNA-based vaccines, 27 were viral vector-based vaccines and 12 DNA vaccines.71 Current clinical trials include viral vector, mRNA and DNA candidates against UKVN priority diseases.72 However, these novel technologies are not yet without issues. For example, RNA vaccines are dependent on ultra-low cold chain transport, a particular challenge in LMIC settings, and immunisation schedules for virus-like particle and DNA vaccines often require three sequential

<sup>64</sup> Wolf J, et al Applying lessons from the Ebola vaccine experience for SARS-CoV-2 and other epidemic pathogens. npj Vaccines 5, 51 (2020). <a href="https://doi.org/10.1038/s41541-020-0204-7">https://doi.org/10.1038/s41541-020-0204-7</a>

<sup>&</sup>lt;sup>65</sup> Saleh A, et al (2021) Vaccine Development Throughout History. Cureus. 13(7):e16635. https://doi.org/10.7759/cureus.16635

<sup>66</sup> Pronker ES, et al (2013) Risk in vaccine research and development quantified. PloS one, 8(3), e57755. https://doi.org/10.1371/journal.pone.0057755

<sup>&</sup>lt;sup>67</sup> Mao W, et al (2023) Comparing research and development, launch, and scale up timelines of 18 vaccines: lessons learnt from COVID-19 and implications for other infectious diseases. BMJ Glob Health 8. https://doi.org/10.1136/bmjqh-2023-012855

<sup>68</sup> Moderna Receives U.S. FDA Approval for RSV Vaccine mRESVIA(R), 31 May 2024.
https://investors.modernatx.com/news/news-details/2024/Moderna-Receives-U.S.-FDA-Approval-for-RSV-Vaccine-mRESVIAR/default.aspx
Accessed 25 June 2024

<sup>&</sup>lt;sup>69</sup> Japan approves first self-amplified mRNA vaccine, 29 Nov 2023. https://www.bioprocessintl.com/regulations/japan-approves-first-self-amplified-mrna-vaccine 2024

<sup>&</sup>lt;sup>70</sup> Bavarian Nordic completes BLA submission to U.S. FDA for its chikungunya vaccine candidate (17 June 2024) <a href="https://www.bavarian-nordic.com/investor/news/news.aspx?news=6960">https://www.bavarian-nordic.com/investor/news/news.aspx?news=6960</a>; Bavarian Nordic receives EMA filing acceptance and validation of the MAA for its Chikungunya vaccine (17 July 2024) <a href="https://www.bavarian-nordic.com/investor/news/news.aspx?news=6964">https://www.bavarian-nordic.com/investor/news/news.aspx?news=6964</a> Accessed 25 July 2024

<sup>71</sup> Thomas & Wessel (2023) The State of Innovation in Vaccines and Prophylactic Antibodies for Infectious Diseases. Bio Industry Analysis for the Biotechnology Innovation Organization (BIO). Available at: <a href="https://www.bio.org/sites/default/files/2024-01/The-State-of-Innovation-in-Vaccines-and-Prophylactic-Antibodies-for-Infectious-Diseases.pdf">https://www.bio.org/sites/default/files/2024-01/The-State-of-Innovation-in-Vaccines-and-Prophylactic-Antibodies-for-Infectious-Diseases.pdf</a> Accessed 16 July 2024

<sup>&</sup>lt;sup>72</sup> For example, <a href="https://clinicaltrials.gov/study/NCT05398796">https://classic.clinicaltrials.gov/ct2/show/NCT04917861</a>, sponsor: Moderna. Accessed 16 July 2024



injections for 6-12 months of protection, thus posing a substantial delivery challenge, especially in rural areas.<sup>73,74</sup>

The development of novel vaccine platforms has also led to a shift in manufacturing technologies, greatly increasing production efficiency and enabling scale-up within a short time frame, as witnessed during the COVID-19 pandemic.<sup>75</sup> Examples are the production of viral vector-based vaccines in suspension cell culture (Oxford University/AstraZeneca), and new mRNA vaccine production platforms involving microbial fermentation and cell-free RNA vaccine synthesis (Pfizer-BioNTech).<sup>76,77</sup> Other examples of improvements to vaccine manufacturing include innovations in purification and analytics for process monitoring.

Current R&D efforts are targeting novel vaccine delivery methods to enhance effectiveness, safety, and accessibility. For instance, vaccine-containing microarray patches (MAPs) eliminate the need for needles, making them more acceptable to recipients and allowing administration by minimally trained healthcare workers.<sup>78</sup>

#### H.3 Recent policy developments relating to vaccine R&D and distribution

As well as technological advances, recent pandemics have triggered policy responses, enabling systems and strategies that accelerate R&D and regulatory approval of new vaccines and manufacturing processes.

The West Africa Ebola virus disease outbreak in 2014-2016, in the absence of vaccines or treatments, refocussed the international community on the threat of epidemics. <sup>79</sup> Although the Ebola virus had been identified four decades earlier, years of research efforts had stalled at the preclinical level. The outbreak triggered internationally coordinated research, and included innovative approaches to clinical development to accelerate R&D, such as the use of a ring vaccination strategy and adaptive platform trial designs. <sup>80</sup> The R&D efforts led to the development of a vaccine, which was however not approved in time to impact patient numbers. Nevertheless, the new vaccine played a crucial role in controlling the subsequent 2018-2020 Ebola virus outbreak in the Democratic Republic of the Congo. <sup>81,82</sup>

<sup>&</sup>lt;sup>73</sup> Ghattas M, et al. (2021) Vaccine Technologies and Platforms for Infectious Diseases: Current Progress, Challenges, and Opportunities. Vaccines 9(12):1490. https://doi.org/10.3390/vaccines9121490

<sup>&</sup>lt;sup>74</sup> Zhang, H et al (2024) Single dose recombinant VSV based vaccine elicits robust and durable neutralizing antibody against Hantaan virus. npj Vaccines 9: 28. <a href="https://doi.org/10.1038/s41541-024-00814-2">https://doi.org/10.1038/s41541-024-00814-2</a>

<sup>75</sup> Buckland, B et al (2024). Vaccine process technology—A decade of progress. Biotechnology and Bioengineering, 1–32. <a href="https://doi.org/10.1002/bit.28703">https://doi.org/10.1002/bit.28703</a>

<sup>&</sup>lt;sup>76</sup> Folegatti et al (2022) Vaccines based on the replication-deficient simian adenoviral vector ChAdOx1: Standardized template with key considerations for a risk/benefit assessment. Vaccine. 40(35). https://doi.org/10.1016/j.vaccine.2022.06.008

<sup>&</sup>lt;sup>77</sup> Gote et al (2023). A Comprehensive Review of mRNA Vaccines. Int. J. Mol. Sci. 24(2700). https://doi.org/10.3390/ijms24032700

<sup>&</sup>lt;sup>78</sup> Choo et al (2023) Microarray patches: scratching the surface of vaccine delivery. Expert Review of Vaccines, 22(1), 937–955. https://doi.org/10.1080/14760584.2023.2270598

<sup>&</sup>lt;sup>79</sup> Marie-Paule Kieny (2018) Lessons learned from Ebola Vaccine R&D during a public health emergency, Human Vaccines & Immunotherapeutics, 14:9, 2114-2115, https://doi.org/10.1080/21645515.2018.1442161

<sup>80</sup> Gsell P et al (2017) Ring vaccination with rVSV-ZEBOV under expanded access in response to an outbreak of Ebola virus disease in Guinea, 2016: an operational and vaccine safety report. The Lancet Infectious Diseases (17) 1276 - 1284. <a href="https://doi.org/10.1016/S1473-3099(17)30541-8">https://doi.org/10.1016/S1473-3099(17)30541-8</a>

<sup>81</sup> Coltart C. et al (2017) The Ebola outbreak, 2013–2016: old lessons for new epidemics. *Phil. Trans. R. Soc. B.* 372(1721) http://doi.org/10.1098/rstb.2016.0297

<sup>82</sup> World Health Organization, Ebola, North Kivu/Ituri, Democratic Republic of the Congo, August 2018 - June 2020 <a href="https://www.who.int/emergencies/situations/Ebola-2019-drc-">https://www.who.int/emergencies/situations/Ebola-2019-drc-</a> Accessed 25 July 2024



The 2014-2016 Ebola virus outbreak also triggered global efforts to shorten the timeframe for emerging infectious diseases (EID) vaccine R&D and regulatory approval more generally. In 2015, the World Health Organization (WHO) developed the R&D Blueprint for Action to Prevent Epidemics at the request of its Member States. 83,84 The Blueprint's objective is to create an R&D environment capable of quickly and effectively responding to outbreaks of EIDs, despite the scientific, logistical and social challenges specific to outbreak situations. To focus R&D efforts, the R&D Blueprint prioritises diseases of greatest epidemic threat for which no, or insufficient, solutions exist.85 It also includes activities targeted at 'developing new norms & standards tailored to the epidemic context', e.g. the development and implementation of innovative study designs for priority pathogens, rapid data sharing mechanisms, and optimisation of the vaccine regulatory landscape. The Ebola outbreak also influenced the US Department of Health and Human Services (HHS) in developing strategies for better regulation to support efficient and effective vaccine development.86 The HSS 2021-2025 National Strategic Plan for Vaccines includes initiatives to improve global regulatory harmonisation, to enhance rapid quality testing procedures, and to increase engagement with developing-country manufacturers to secure vaccine supply.

regulatory Subsequently, innovative approaches to translation, approval commercialisation facilitated the approval and distribution of the first COVID-19 vaccines within just 11 months. For example, new models pioneered by the UK Vaccine Taskforce enabled the world's first COVID-19 vaccine to be delivered to a National Health Service (NHS) patient outside of a clinical trial on 8th December 2020.87 These included adaptive trial designs (e.g. the RECOVERY trial), accelerated regulatory approval by the Medicines and Healthcare Products Regulatory Agency (MHRA) (e.g. rolling reviews), and data sharing across organisations and sectors to expedite R&D, procurement, manufacturing, and distribution. This required effective collaboration between various groups including policymakers in national governments, vaccine industry professionals, regulatory authorities, and expert advisors.<sup>88,89</sup> These activities are seen by many as exemplar of effective interorganisational collaboration between stakeholder groups involved in the rapid translation of vaccine R&D and is being used by UK government as a model for tackling health challenges in other areas.%

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<sup>83</sup> WHO (2016) An R & D Blueprint for Action to Prevent Epidemics – Plan of Action. https://cdn.who.int/media/docs/default-source/blue-print/an-randd-blueprint-for-action-to-prevent-epidemics.pdf Accessed 16 July 2024

<sup>84</sup> Kieny M & Rägo L. (2016). Regulatory policy for research and development of vaccines for public health emergencies. Expert Review of Vaccines (15) 1075 - 1077. <a href="https://doi.org/10.1080/14760584.2016.1188695">https://doi.org/10.1080/14760584.2016.1188695</a>

<sup>85</sup> World Health Organization, Prioritizing diseases or research and development in emergency contexts. Available at: https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts. Accessed 22 June 2024

<sup>86</sup> US Department of Health and Human Services. (2021). Vaccines National Strategic Plan 2021–2025. https://www.hhs.gov/sites/default/files/HHS-Vaccines-Report.pdf Accessed 16 July 2024

<sup>87</sup> NHS England (2020) Landmark moment as first NHS patient receives COVID-19 vaccination. Available at: https://www.england.nhs.uk/2020/12/landmark-moment-as-first-nhs-patient-receives-covid-19-vaccination/ Accessed 17 June 2024

<sup>88</sup> DHSC (2023) A Review of the UK Vaccine Taskforce, Research and analysis. Available at: https://www.gov.uk/government/publications/a-review-of-the-vaccine-taskforce/a-review-of-taskforce/a-review-o

<sup>&</sup>lt;sup>89</sup> Bingham (2022) The Long Shot: The Inside Story of the Race to Vaccinate Britain. *Oneworld Publications*. ISBN: 9780861545643 Accessed 21 June 2024

<sup>90</sup> GOV.UK press release (2022) Government to use Vaccine Taskforce model to tackle health challenges. Available at: <a href="https://www.gov.uk/government/news/government-to-use-vaccine-taskforce-model-to-tackle-health-challenges">https://www.gov.uk/government/news/government-to-use-vaccine-taskforce-model-to-tackle-health-challenges</a> Accessed 24 July 2024



Policy instruments such as Advance Market Commitments (AMCs) and Advanced Purchase Commitments (APCs) reduce vaccine developers' financial risk as funders commit to procuring vaccines before development and regulatory approval are completed, contingent on meeting specific conditions. <sup>91</sup> In 2007, a group of countries and the Gates Foundation pledged US\$1.5 billion toward a pilot AMC for a new vaccine against pneumococcus, to incentivise completion of late-stage clinical trials as well as production capacity to serve the low-income market. <sup>92</sup> In response to the Ebola virus outbreak, Gavi, the Vaccine Alliance (Gavi) and Merck signed an APC towards the development of Merck's Ebola Zaire virus vaccine. <sup>93,94</sup> Both the AMC and APC mechanisms were used during the COVID-19 pandemic to incentivise vaccine development, e.g. the COVAX AMC led by Gavi, The Coalition for Epidemic Preparedness Innovations (CEPI), and the WHO, and APCs from the US government (Operation Warp Speed) and the EU with individual manufacturers. <sup>95</sup>

However, while vaccine development and distribution of COVID-19 vaccines in developed countries was highly accelerated, widespread distribution of COVID-19 vaccines in LMICs lagged behind. Excessive procurement by wealthy nations hindered the global COVAX initiative in achieving its aim of ensuring equitable access to COVID-19 vaccines for all countries. While it is important that policymakers and experts draw on the successes in fighting the COVID-19 pandemic, shortcomings need to be addressed to ensure equitable access to vaccines. This includes securing sufficient supply by facilitating and funding the expansion of scale-up capacity for traditional and new vaccine technologies in LMICs, tech transfer of new technologies to LMIC producers, and enhancing LMIC national regulatory capacity.

#### H.4 Progress in vaccine R&D targeting UKVN priority diseases

Vaccine candidates targeting the UKVN's priority disease areas are in various stages of development. Table 30 provides an overview of vaccine candidates in clinical development and vaccines that have been submitted for or gained regulatory approval. The twelve priority diseases are Chikungunya, Crimean-Congo Haemorrhagic Fever (CCHF), Ebola, Hantavirus, Lassa, Marburg, MERS, Nipah, Plague (Yersinia pestis), Q Fever (Coxiella burnetii), Rift Valley Fever and Zika.

#### H.5 Status of clinical development of UKVN priority diseases

Of the twelve priority diseases, vaccines against four diseases have been approved by one or more regulatory agencies:

<sup>&</sup>lt;sup>91</sup> Towse A. et al (2021) How Should the World Pay for a Coronavirus Disease (COVID-19) Vaccine? Value in Health. 24(5). https://doi.org/10.1016/j.jval.2020.12.008

<sup>&</sup>lt;sup>92</sup> Snyder C. et al (2011) Economic perspectives on the advance market commitment for pneumococcal vaccines. Health affairs, 30 (8): 1508-17. https://doi.org/10.1377/hlthaff.2011.0403

<sup>93</sup> Noad R. et al. Scoping report for the UK Vaccine Network Options for investment in vaccines and vaccine technology for infectious diseases with epidemic potential. Available at: <a href="https://researchonline.lshtm.ac.uk/id/eprint/4665413/7/Noad\_etal\_2021\_Scopingreport-for-the-uk.pdf">https://researchonline.lshtm.ac.uk/id/eprint/4665413/7/Noad\_etal\_2021\_Scopingreport-for-the-uk.pdf</a> Accessed 7 June 2024

<sup>94</sup> Gavi website, Ebola vaccine purchase commitment from Gavi to prepare for future outbreaks. Available at: https://www.gavi.org/news/media-room/ebola-vaccine-purchasing-commitment-gavi-prepare-future-outbreaks Accessed 14 August 2024

<sup>95</sup> Towse A. et al (2021) How Should the World Pay for a Coronavirus Disease (COVID-19) Vaccine? Value in Health. 24(5). https://doi.org/10.1016/j.jval.2020.12.008

<sup>%</sup> de Bengy Puyvallée A, Storeng KT. COVAX, vaccine donations and the politics of global vaccine inequity. Global Health. 2022 Mar 5;18(1):26. <a href="https://doi.org/10.1186/s12992-022-00801-z">https://doi.org/10.1186/s12992-022-00801-z</a>

<sup>&</sup>lt;sup>97</sup> Hotez PJ et al (2023) COVID-19 vaccines and the pandemic: lessons learnt for other neglected diseases and future threats. BMJ Global Health 8(6):e011883. <a href="https://doi.org/10.1136/bmjgh-2023-011883">https://doi.org/10.1136/bmjgh-2023-011883</a>



- Four vaccines against the Zaire strain of Ebola virus (two only approved in China/Russia)
- Two vaccines against Chikungunya: Valneva's IXCHIQ®, approved by the US Food and Drug Administration, FDA and the European Medicines Agency, EMA, in 2023/202, and Bavarian Nordic's VIMKUNYA™ approved in 2025).<sup>98,99</sup>
- Two vaccines against Yersinia pestis (plague), approved in Russia/China)
- One vaccine against Coaxiella burnetii (Q Fever), approved in Australia

Vaccine candidates for all diseases except Q Fever are in clinical development, either in ongoing clinical trials<sup>100</sup> or between clinical trial phases.

Table 30 Clinical development of vaccines targeting UKVN priority pathogens

Target disease	Number of vaccine candidates	Region of developer / manufacturer	Platform categories	Stage of development (no. per stage)
Ebola	15	Europe, Russia, USA, China, Japan	Viral vector, inactivated/live- attenuated, protein- based subunit, DNA	Approved (4) Phase II (1) Phase I (10)
Marburg	5	USA, Europe	Viral vector, DNA	Phase II (1) Phase I (4)
Lassa	5	USA, Europe	Viral vector, inactivated, DNA	Phase II (1) Phase I (4)
CCHF	4	UK, Europe	Viral vector, DNA	Phase I (4)
Chikungunya	9	Europe, India, USA	Viral vector, inactivated/live- attenuated, protein- based subunit, particle- based subunit, mRNA	Approved (2) Phase II/III (2) Phase I (5)
Zika	16	UK, USA, India, Europe, Japan	Viral vector, inactivated/live- attenuated, protein- based subunit, DNA, mRNA	Phase II (3) Phase I (13)
Rift Valley Fever	3	Europe, UK, USA	Viral vector, inactivated/live- attenuated	Phase II (1) Phase I/II (1) unknown

<sup>&</sup>lt;sup>98</sup> Flandes, X et al (2024) Vaccine value profile for Chikungunya. Vaccine 42.
<a href="https://doi.org/10.1016/j.vaccine.2023.07.069">https://doi.org/10.1016/j.vaccine.2023.07.069</a>; Valneva Receives EMA's Positive CHMP Opinion for its Chikungunya Vaccine (31 May 2024). Available at: <a href="https://valneva.com/press-release/valneva-receives-emas-positive-chmp-opinion-for-its-chikungunya-vaccine/">https://valneva.com/press-release/valneva-receives-emas-positive-chmp-opinion-for-its-chikungunya-vaccine/</a> Accessed 25 July 2024; Valneva Receives Marketing Authorization in Europe for the World's first Chikungunya Vaccine, IXCHIQ (1 July 2024). Available at: <a href="https://valneva.com/press-release/valneva-receives-marketing-authorization-in-europe-for-the-worlds-first-chikungunya-vaccine-ixchiq">https://valneva.com/press-release/valneva-receives-marketing-authorization-in-europe-for-the-worlds-first-chikungunya-vaccine-ixchiq</a> Accessed 14 August 2024

<sup>99</sup> Bavarian Nordic completes BLA submission to U.S. FDA for its chikungunya vaccine candidate (17 June 2024) <a href="https://www.bavarian-nordic.com/investor/news/news.aspx?news=6960">https://www.bavarian-nordic.com/investor/news/news.aspx?news=6960</a>; Bavarian Nordic receives EMA filing acceptance and validation of the MAA for its Chikungunya vaccine (17 July 2024) <a href="https://www.bavarian-nordic.com/investor/news/news.aspx?news=6964">https://www.bavarian-nordic.com/investor/news/news.aspx?news=6964</a> Accessed 25 July 2024

 $<sup>^{\</sup>rm 100}$  This includes trials which may have completed but have not reported findings.



MERS	4	USA, Europe, Russia	Viral vector, DNA	Phase II (1) Phase I (3)
Nipah	4	USA, UK	Viral vector, protein- based subunit, mRNA	Phase I (4)
Hantavirus	2	USA	DNA	Phase II (1) Phase I (1)
Plague (Yersinia pestis)	7	USA, UK, Russia, China	Viral vector,inactivates/live- attenuated, protein- based subunit	Approved (2) Phase II (2) Phase I (3)
Q Fever (Coxiella burnetiid)	2	USA	Inactivated/live- attenuated	Approved (1) Phase II (1)

Sources: WHO International Clinical Trials Registry Platform (ICTRP) Search Portal. 101 Triangulated with 102,103,104,105,106,107,108,109,110,111

Two vaccine candidates were withdrawn after results fell short (Inovio's DNA vaccine candidates for MERS and Lassa), and the development of one candidate was terminated after competitors' vaccines "won the race to the finish line", demonstrating the risky nature and high

<sup>101</sup> WHO International Clinical Trials Register Platform (ICTRP). Available at: <a href="https://trialsearch.who.int/">https://trialsearch.who.int/</a> Accessed May 2025

<sup>&</sup>lt;sup>102</sup> Flandes, X et al (2024) Vaccine value profile for Chikungunya. Vaccine 42. https://doi.org/10.1016/j.vaccine.2023.07.069

<sup>103</sup> Malik S, et al (2023) Ebola Virus Disease Vaccines: Development, Current Perspectives & Challenges. Vaccines (Basel) 11(2):268. https://doi.org/10.3390/vaccines11020268

<sup>&</sup>lt;sup>104</sup> Afzal, S et al (2023) Hantavirus: an overview and advancements in therapeutic approaches for infection. Front. Microbiol. 14. <a href="https://doi.org/10.3389/fmicb.2023.1233433">https://doi.org/10.3389/fmicb.2023.1233433</a>

<sup>&</sup>lt;sup>105</sup> Sulis, G et al (2023). Lassa fever vaccine candidates: A scoping review of vaccine clinical trials. Tropical medicine & international health: TM & IH, 28(6), 420–431. https://doi.org/10.1111/tmi.13876

Nane Manohar MP (2023) Advancements in Marburg (MARV) Virus Vaccine Research With Its Recent Reemergence in Equatorial Guinea and Tanzania: A Scoping Review. Cureus 15(7):e42014.
https://doi.org/10.7759/cureus.42014

<sup>&</sup>lt;sup>107</sup> Kandeel M, et al (2023) Safety and immunogenicity of the ChAdOx1, MVA-MERS-S, and GLS-5300 DNA MERS-CoV vaccines. Int Immunopharmacol. 118:109998. https://doi.org/10.1016/j.intimp.2023.109998

<sup>108</sup> Rodrigue, V et al (2024) Current progress towards prevention of Nipah and Hendra disease in humans: A scoping review of vaccine and monoclonal antibody candidates being evaluated in clinical trials. TMIH 29, <a href="https://doi.org/10.1111/tmi.13979">https://doi.org/10.1111/tmi.13979</a>

<sup>109</sup> Hartley, L et al (2022) The efficacy, safety, and immunogenicity of plague vaccines: A systematic literature review. Current Research in Immunology 4. <a href="https://doi.org/10.1016/j.crimmu.2023.100072">https://doi.org/10.1016/j.crimmu.2023.100072</a>

<sup>&</sup>lt;sup>110</sup> Alkan, C et al (2023) Advancements in Rift Valley fever vaccines: a historical overview and prospects for next generation candidates. npj Vaccines 8, 171. <a href="https://doi.org/10.1038/s41541-023-00769-w">https://doi.org/10.1038/s41541-023-00769-w</a>

<sup>&</sup>lt;sup>111</sup> Zhe-Yu Peng et al (2024) A review on Zika vaccine development. Pathogens and Disease 82: ftad036, https://doi.org/10.1093/femspd/ftad036



failure rates of vaccine R&D.<sup>112,113</sup> There continues to be no candidates for Q Fever in clinical development.

## H.6 Progress in Disease X preparedness

In addition to the twelve specific disease pathogens, UKVN also targets 'Disease X', a term coined by the WHO Blueprint team representing 'a pathogen currently unknown to cause human disease' that could however lead to an international epidemic.<sup>114</sup> Disease X research is defined as 'cross-cutting R&D preparedness that is also relevant for an unknown disease'. It hence includes R&D on platform technologies, as well as fundamental research on the biology of pathogen families, immunology, and epidemiology.

The rapid development of vaccines for the COVID-19 pandemic represents tremendous progress in responding to Disease X outbreaks and illustrates the impact of Disease X R&D. Vaccine candidates were designed, produced and tested within unprecedented timeframes. For example, after the genetic sequence of the SARS-CoV-2 virus was released in January 2020, BioNTech rapidly developed several mRNA vaccine candidates, and partnered with Pfizer to co-develop and scale up production by mid-March 2020. The first mRNA vaccine candidate began human clinical trials by late July 2020. Research conducted in response to the MERS epidemic on the Arabian Peninsula underpinned SARS-CoV-2 R&D, as it provided an understanding of how to stabilise the spike protein in order to elicit the appropriate type of antibodies. Hence, even though SARS-CoV-2 was an unknown pathogen when it emerged (a Disease X), vaccine development was sped up considerably by preceding research on vaccine platforms and the broader coronavirus family.

Vaccine candidates against UKVN priority diseases were developed on a range of platforms, e.g., viral vector-, mRNA- and DNA-based vaccines, including before the COVID-19 pandemic (see Table 30). This research contributed to the rapid progress during the COVID-19 pandemic: For example, the 2014 Ebola virus outbreak led to the development of a vaccine using the novel ChAd-Ox1 viral vector platform, which was subsequently used for vaccine R&D targeting a range of UKVN priority pathogens (Chikungunya, Rift Valley Fever – RVF, Lassa). This work in turn accelerated the development of the COVID-19 vaccine marketed by AstraZeneca.<sup>117</sup>

#### Challenges to vaccine R&D and access

<sup>112</sup> Fierce Biotech website, Inovio drops Lassa, MERS vaccines as clinical trial data fall short, gutting infectious disease pipeline. (18 November 2024) Available at: <a href="https://www.fiercebiotech.com/biotech/inovio-drops-lassa-mers-vaccines-clinical-data-fall-short-gutting-infectious-disease">https://www.fiercebiotech.com/biotech/inovio-drops-lassa-mers-vaccines-clinical-data-fall-short-gutting-infectious-disease</a> Accessed 14 August 2024

<sup>113</sup> Fierce Biotech website, Merck admits defeat in race with Valneva to get first chikungunya vaccine to market. (2 February 2023) <a href="https://www.fiercebiotech.com/deals/merck-admits-defeat-race-valneva-get-first-chikungunya-vaccine-market">https://www.fiercebiotech.com/deals/merck-admits-defeat-race-valneva-get-first-chikungunya-vaccine-market</a> Accessed 28 January 2025

<sup>114</sup> Chapman et al (2022) Landscape of Emerging Infectious Disease Research and Development. G-FINDER website. Available at: https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2022/06/16191104/2022-G-FINDER-EID-Report.pdf Accessed 6 June 2024

<sup>115</sup> Pfizer website, Shot of a Lifetime: How Pfizer and BioNTech Developed and Manufactured a COVID-19 Vaccine in Record Time. Available at:

https://www.pfizer.com/news/articles/shot of a lifetime how pfizer and biontech developed and manufacture d a covid 19 vaccine in record time Accessed 14 August 2024

<sup>&</sup>lt;sup>116</sup> Excler J-L et al (2023) Factors, enablers and challenges for COVID-19 vaccine development. BMJ Glob Health 8:e011879. https://doi.org/10.1136/bmjgh-2023-011879

<sup>&</sup>lt;sup>117</sup> The Jenner Institute, Development of the ChAdOx vaccine platform. Available at <a href="https://www.jenner.ac.uk/about/the-oxford-astrazeneca-covid-19-vaccine/ChAdOx-platform">https://www.jenner.ac.uk/about/the-oxford-astrazeneca-covid-19-vaccine/ChAdOx-platform</a> Accessed 14 August 2024

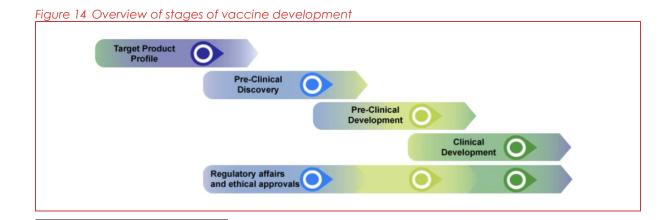


#### H.7 Challenges to vaccine R&D

The process of translating basic research into a commercially available product is a lengthy and scientifically challenging process with a high likelihood of failure. Translational research has to solve scientific and technical challenges (e.g. understanding a disease mechanism, ensuring the stability of vaccine candidates) as well as tackling 'non-scientific' challenges such as insufficient R&D funding, a lack of infrastructure and translational research skills, regulatory and administrative burden, difficulties collaborating across scientific fields and sectors, and a lack of incentives for academic researchers to translate an innovation. <sup>118,119</sup> This results in innovations getting 'stuck' along the development pathway.

These challenges also apply to vaccines R&D. A 2021 consultation of 93 experts on key barriers to vaccine development highlighted issues relevant to all areas of translational research: "Academia not being able to progress beyond proof of principle" was among the barriers of highest impact, leading to "vaccine candidates and technologies getting stuck in the discovery and realisation phase". Many funders of translational research aim to address these barriers by targeting funding at research that progresses vaccine candidates through early-stage clinical trials. 121

The UKVN created a Vaccine Development Process Map to guide early discovery and development scientists through the key stages in vaccine development. <sup>122</sup> The tool highlights potential bottlenecks in the various development phases, focussing on those that may be improved by corrective action or investments by governments, research funders and policy makers. Key barriers were categorised into research, infrastructure, or policy. This broad generic framework was then applied to map the specific development pathways and challenges for individual UKVN priority pathogens: MERS, Zika and the plague.



<sup>118</sup> MRC Translational Research 2008-2018, Evaluation Report (2019). Available at: <a href="https://www.ukri.org/wp-content/uploads/2022/01/MRC170122-TranslationalResearchEvaluationReport.pdf">https://www.ukri.org/wp-content/uploads/2022/01/MRC170122-TranslationalResearchEvaluationReport.pdf</a> Accessed 21 June 2024

<sup>119</sup> Lander & Atkinson-Grosjean (2011) Translational science and the hidden research system in universities and academic hospitals: A case study. Social Science & Medicine. 72(4). https://doi.org/10.1016/j.socscimed.2010.11.019

<sup>120</sup> Janse M et al (2021) Barriers Influencing Vaccine Development Timelines, Identification, Causal Analysis, and Prioritization of Key Barriers by KOLs in General and Covid-19 Vaccine R&D. Front Public Health 9:612541. https://doi.org/10.3389/fpubh.2021.612541

<sup>121</sup> Projects supported by DHSC through the UK Vaccine Network (2019). Available at: https://www.gov.uk/government/groups/uk-vaccines-network Accessed 14 June 2024

<sup>&</sup>lt;sup>122</sup> UKVN Working Group 3 focus: "To understand the challenges in vaccine development and the key rate limiting steps for any given vaccine in development."



Source: UK Vaccine R&D Network: Vaccine Development Process Map

Table 31 Summary of vaccine development barriers

R&D stage	Barriers that can be improved through	:		
Pre-clinical discovery	Research spending	Policy changes	Infrastructure investment	
	<ul><li>Pathogen biology, incl.:</li><li>Human-host immunology</li><li>Pathogen challenge model</li></ul>	Freedom to operate		
Pre-clinical development	<ul> <li>Process development incl.:</li> <li>Critical process parameters</li> <li>Critical quality attributes</li> <li>Adjuvants and formulation</li> <li>Suitable animal model</li> </ul>		Scale-up and clinical manufacture     GMP bulk     GMP fill-finish	
Clinical development		<ul> <li>GMO regulation</li> <li>International trial sites and approval by National Regulatory Authorities</li> <li>Regulatory and ethical approval</li> </ul>		

Source: Adapted from Drury et al (2019). 123 Note: GMP: Good Manufacturing Practice; GMO: Genetically Modified Organism

At early stages of discovery, an initial barrier is building an understanding of the pathogen's basic biological properties, with an associated bottleneck in determining the most appropriate human-host immunological response to be considered. During pre-clinical development, major barriers include the lack of a suitable animal model, especially for EIDs, and challenges related to process development. For example, developers need to ensure that vaccine manufacturing is scalable, a time-consuming process for traditional vaccine technologies, and that the analytics to verify vaccine quality are in place (critical process parameters / critical quality attributes). Novel vaccine platforms such as mRNA vaccines are likely to reduce these challenges, holding the potential for faster, scalable and lower cost production (see section H.2).

During clinical development, such as international clinical trials, key barriers include delays in setting up trial sites and obtaining ethical approval, and lengthy timeframes for regulatory approval by national authorities including complex regulatory requirements for vaccines that fall into the genetically modified organism (GMO) category.

In 2021, the UKVN Scoping Report examined remaining technical gaps in vaccine development that were poorly funded at the time and which UKVN funding could address

123 Drury, Jolliffe, and Mukhopadhayay (2019) Process mapping of vaccines: Understanding the limitations in current response to emerging epidemic threats. *Vaccine*, 37 (17), <a href="https://www.vaccinedevelopment.org.uk/">https://www.vaccinedevelopment.org.uk/</a> Accessed 18 June 2024

<sup>124</sup> Drury, Jolliffe, and Mukhopadhayay (2019) Process mapping of vaccines: Understanding the limitations in current response to emerging epidemic threats. Vaccine, 37 (17), https://doi.org/10.1016/j.vaccine.2019.01.050. https://www.vaccinedevelopment.org.uk/ Accessed 18 June 2024



(Table 32). 125 Given the timing, the study incorporated insights from the experience of the development, manufacture and delivery of vaccines for COVID-19. For example, the 2019 UKVN Vaccine Development Process Map had highlighted 'critical process parameters' as a key barrier; at the time, platform manufacturing technologies such as viral vector-based and mRNA platforms had not yet reached maturity. By the time the scoping report was published in 2021, several vaccines based on these platforms had been approved. The technical barriers highlighted took account of this progress and included the need for research into deployment of rapid production platforms, funding for production facilities and knowledge transfer to LMICs (see section H.8). The greatest number of identified gaps relevant to vaccine manufacture and deployment, based on learning from the COVID-19 pandemic on the need to ensure prompt and equitable vaccine access for LMIC populations.

Table 32 Technical gaps for future vaccine development

Category	Identified Gap*	
Overarching	Funding to allow vaccines to progress to completion of phase 2 clinical trials even during inter-epidemic periods.	
ovoruioig	Vaccines for livestock and wildlife for zoonotic diseases.	
	Funding to enable and improve Good Manufacturing Practice (GMP) vaccine manufacture at scale for prototype vaccines.	
	Research into deployment of rapid production platforms for vaccines.	
Manufacture and Deployment	Research into deployment of rapid production platforms for input materials (plasmids, linear DNA, enzymes, nucleotides, formulation ingredients).	
	Funding for GMP production facilities (including LMICs).	
	Knowledge transfer especially for RNA vaccines (LMICs).	
Technical Improvements to	Development of vaccines with alternative delivery routes (e.g., oral or nasal).	
Vaccines	Vaccines that are stable at 40 °C.	
Testing and Immunology	Identification of animal models relevant to vaccine development for priority diseases.	
resing and immunology	Standardised diagnostic tests for priority diseases.	

Source: Noad et al (2021)<sup>126</sup> Note: \*As previously highlighted by Drury et al (2019), the panel also identified existing intellectual property as a potential barrier to vaccine R&D, e.g. specifically relating to mRNA vaccine platforms, but that a detailed investigation was beyond the scope of the study.

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Noad R. et al. Scoping report for the UK Vaccine Network: Options for investment in vaccines and vaccine technology for infectious diseases with epidemic potential. Available at: <a href="https://researchonline.lshtm.ac.uk/id/eprint/4665413/7/Noad\_etal\_2021\_Scopingreport-for-the-uk.pdf">https://researchonline.lshtm.ac.uk/id/eprint/4665413/7/Noad\_etal\_2021\_Scopingreport-for-the-uk.pdf</a> Accessed 7

<sup>&</sup>lt;sup>126</sup> Noad R. et al. Scoping report for the UK Vaccine Network Options for investment in vaccines and vaccine technology for infectious diseases with epidemic potential. Available at:
<a href="https://researchonline.lshtm.ac.uk/id/eprint/4665413/7/Noad\_etal\_2021\_Scopingreport-for-the-uk.pdf">https://researchonline.lshtm.ac.uk/id/eprint/4665413/7/Noad\_etal\_2021\_Scopingreport-for-the-uk.pdf</a> Accessed 7
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The pace of vaccine development in 2020/21 in response to the COVID-19 pandemic illustrated that it is possible to overcome previous time-consuming barriers. 127,128 However, the unprecedented speed from inception to approval and implementation was enabled by a combination of factors:

- The magnitude of impact on health, economic and social levels worldwide, focussing global attention on the pandemic
- Enormous financial investment, reducing financial risks for vaccine developers
- Massive global demand & use of financial instruments (APC & AMCs) securing markets for vaccines
- Substantial previous research on related coronaviruses (SARS, MERS), providing a better understanding of the virus' biology, possible transmission mechanisms and virus target for inducing protective immune responses
- Substantial previous research on mRNA and viral vector technology, which had already led to progress in manufacturing process development
- Accelerated clinical testing, such as adaptive clinical trial designs with key phases of the trial process conducted in parallel and harmonised clinical trial protocols, with experience gathered during the Ebola virus epidemic
- Expedited regulatory processes such as rolling regulatory reviews, allowing faster approval and distribution
- Global initiatives and coordination, with extensive collaboration and data sharing among scientists, manufacturers, and governments

Some of these factors are now 'available' to accelerate future vaccine development, e.g. novel platform technologies and new models for faster clinical testing, regulatory approval, and global cross-sector collaboration. Other factors provided COVID-19 vaccine developers with a head start and incentives that may not be replicable for tackling other pathogens, e.g. many years of prior research had already identified a coronavirus spike protein that could trigger an effective antibody response.<sup>129</sup> The COVID-19 virus also represented an unusually attractive pathogen for industry: Unlike COVID-19, most epidemics are relatively short-lived, geographically limited, and mainly affect underserved populations.<sup>130</sup> However, from a public health perspective, pandemics could be prevented more efficiently if vaccine development tackled outbreaks when and where they arise, using small-scale interventions, and rarely the (profitable) scaled-up production and deployment of health technologies.

### H.8 Challenges in LMICs to vaccine access and uptake

Compared with high-income countries (HICs), LMICs face increased challenges to ensure proper access to vaccines, related to procurement, distribution, and uptake of vaccines. These include:

<sup>&</sup>lt;sup>127</sup> Excler J-L et al (2023) Factors, enablers and challenges for COVID-19 vaccine development. BMJ Glob Health 8:e011879. https://doi.org/10.1136/bmjgh-2023-011879

<sup>128</sup> Mao W, et al (2023) Comparing research and development, launch, and scale up timelines of 18 vaccines: lessons learnt from COVID-19 and implications for other infectious diseases. BMJ Glob Health 8. <a href="https://doi.org/10.1136/bmjah-2023-012855">https://doi.org/10.1136/bmjah-2023-012855</a>

<sup>&</sup>lt;sup>129</sup> Excler J-L et al (2023) Factors, enablers and challenges for COVID-19 vaccine development. BMJ Glob Health 8:e011879. <a href="https://doi.org/10.1136/bmjgh-2023-011879">https://doi.org/10.1136/bmjgh-2023-011879</a>

<sup>&</sup>lt;sup>130</sup> Farlow, A. et al. (2023) The Future of Epidemic and Pandemic Vaccines to Serve Global Public Health Needs. Vaccines 2023, 11, 690. <a href="https://doi.org/10.3390/vaccines11030690">https://doi.org/10.3390/vaccines11030690</a>



- **Financial constraints**: LMICs have limited financial resources to purchase vaccines, especially when in competition with HICs as illustrated by COVAX. This financial constraint also impacts LMICs' ability to maintain vaccine infrastructure, facilitate vaccination campaigns, and build regulatory expertise.
- Lack of effective healthcare infrastructure: An effective healthcare infrastructure is necessary to efficiently distribute vaccines. 131 In LMICs, the healthcare infrastructure is often inadequate, especially for reaching target populations in remote or hard-to-reach areas. This presents a challenge to distribution, such as meeting cold-chain requirements for the 'last mile', i.e. the transport of vaccines from central storage facilities to the point of administration. Hence, some vaccines that are routinely used in HICs are not/less suitable for distribution in LMICs.
- Fewer opportunities to test and troubleshoot vaccine rollout: Infrequent international vaccine supply to LMICs and unpredictability of outbreaks reduces the frequency of opportunities to develop vaccines (see Ebola Sudan virus example, section H.1), to build out internal distribution networks and to troubleshoot infrastructural challenges. 132
- Complex stakeholder coordination for distribution: Vaccine delivery in LMICs requires coordination between many stakeholder groups, particularly for reaching remote communities and populations living in conflict areas who cannot visit vaccination centres.<sup>133</sup>
- Challenges in behaviour and attitudes to vaccines: Vaccine hesitancy is a complex issue in LMICs as well as HICs, driven by different sets of local factors and beliefs. For example, in a study of vaccine uptake in rural communities in Zambia, traditional remedies, alcohol use and religious beliefs emerged as drivers of vaccine hesitancy, likely reinforced by a background of distrust towards western medicine. 134 Lack of health literacy and a poor understanding of the importance of immunisation are also cited as factors. 135 To address issues with hesitancy and initial uptake, vaccination strategies often start by targeting healthcare workers in LMICs, who are easily identifiable, closely connected to healthcare systems, and easier to inform. 136 Furthermore, they are more likely to become exposed to certain diseases and therefore are a high-priority group to protect. However, hesitancy may be present even in this group, e.g. as reported during the COVID-19 pandemic. 137

Some of these barriers can be addressed through innovation. The Vaccine Innovation Prioritisation Strategy (VIPS), a partnership between Gavi, WHO, the Bill & Melinda Gates

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<sup>&</sup>lt;sup>131</sup> Reza et al (2023) Local distribution infrastructure and robust vaccine manufacturing facilities in LMICs should be prioritised to tackle ongoing and future pandemic risk. The Lancet Regional Health. 11 (100158). https://doi.org/10.1016/j.lansea.2023.100158

<sup>&</sup>lt;sup>132</sup> Reza et al (2022) Why are vaccination rates lower in low and middle income countries, and what can we do about it? BMJ; 378: e069506 <a href="https://doi.org/10.1136/bmj-2021-069506">https://doi.org/10.1136/bmj-2021-069506</a>

<sup>133</sup> Understanding the behavioural and social drivers of vaccine uptake - WHO position paper - May 2022. Available at: https://iris.who.int/bitstream/handle/10665/354458/WER9720-eng-fre.pdf Accessed 20 June 2024

<sup>&</sup>lt;sup>134</sup> Pugliese-Garcia et al (2018) Factors influencing vaccine acceptance and hesitancy in three informal settlements in Lusaka, Zambia. Vaccine. 36(37). <a href="https://doi.org/10.1016/j.vaccine.2018.07.042">https://doi.org/10.1016/j.vaccine.2018.07.042</a>

<sup>135</sup> Biasio (2017) Vaccine hesitancy and health literacy. Hum Vaccin Immunother. 13(3) https://doi.org/10.1080/21645515.2016.1243633

<sup>&</sup>lt;sup>136</sup> McKinsey (2023) 'None are safe until all are safe': COVID-19 vaccine rollout in low- and middle-income countries. Available at: <a href="https://www.mckinsey.com/industries/healthcare/our-insights/none-are-safe-until-all-are-safe-covid-19-vaccine-rollout-in-low-and-middle-income-countries">https://www.mckinsey.com/industries/healthcare/our-insights/none-are-safe-until-all-are-safe-covid-19-vaccine-rollout-in-low-and-middle-income-countries</a> Accessed 20 June 2024

<sup>&</sup>lt;sup>137</sup> Noushad, M et al (2022) A Global Survey of COVID-19 Vaccine Acceptance Among Healthcare Workers. Frontiers in Public Health. 9. https://doi.org/10.3389/fpubh.2021.794673



Foundation (BMGF), UNICEF, and PATH, developed a system for evaluating and prioritising new vaccine technologies that address immunisation barriers in LMICs. Published in 2020, the strategy brings together insights from research on country needs and assessment of potential benefits of innovations to guide investment decisions. It concluded with the prioritisation of three innovations/approaches: 1) a novel delivery device, microarray patches (MAPs); 2) heat-stable and controlled temperature chain (CTC)-qualified vaccines, which can be used outside of the cold chain; and 3) barcodes on primary packaging, e.g. to reduce the risk of falsified vaccines and improve patient safety.

Funders are investing in developing local capacity to reduce LMICs' reliance on HICs for vaccine supply and the complexity of transportation and distribution. For example, a key pillar of CEPI's 2022-2026 strategy is to engage with LMICs to address national vulnerabilities due to a lack of R&D and manufacturing capacity and to strengthen supply chains and legislation (see section H.11.1). Similarly, the EU and Gavi are investing in building manufacturing capacity in Africa (see section H.11.2).

The COVID-19 pandemic also highlighted the need to develop intellectual property (IP) waivers and means of effective technology transfer to facilitate distribution of vaccines to LMICs. <sup>139</sup> IP rights provide protection for novel technologies, controlling who is authorised to produce a vaccine and how much they can manufacture, thus impacting availability. After vaccine shortages in LMICs due to HIC purchasing available stock, South Africa and India, supported by 100 countries, proposed a three-year IP rights waiver for COVID-19 health products and technologies In October 2020. <sup>140</sup> However, the proposal was opposed by the UK and EU, citing the positive role that IP rights had played in generating innovative vaccines against COVID-19. <sup>141</sup> A compromise deal was announced in June 2022, allowing developing countries to authorise the use of patented materials and ingredients for the manufacture of Covid-19 vaccines without the consent of IP rights holders to produce vaccines for domestic and eligible markets for a five-year period. <sup>142,143</sup> This waiver was criticised for not going far enough in addressing the challenges faced by many LMICs. <sup>144</sup> After failing to reach a conclusion by the originally intended date of May 2024, WHO member states continue to negotiate a new agreement (the 'Pandemic Treaty'). <sup>145</sup>

The international funding landscape for vaccine R&D

<sup>&</sup>lt;sup>138</sup> CEPI 2022-2026 strategy. Available at: <a href="https://static.cepi.net/downloads/2023-12/CEPI-2022-2026-Strategy-v3-Jan21\_0.pdf">https://static.cepi.net/downloads/2023-12/CEPI-2022-2026-Strategy-v3-Jan21\_0.pdf</a> Accessed 21 June 2024

<sup>&</sup>lt;sup>139</sup> Erfani P. et al. (2021) Intellectual property waiver for covid-19 vaccines will advance global health equity. BMJ. 374. https://doi.org/10.1136/bmi.n1837

<sup>140</sup> WTO (2020) Waiver from certain provisions of the TRIPS agreement from the prevention, containment and Treatment of COVID-19. Available at:
<a href="https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True">https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True</a>
Accessed 24 July 2024

<sup>&</sup>lt;sup>141</sup> House of Commons Research Briefing, Loft (2022) Waiving intellectual property rights for Covid-19 vaccines. https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf Accessed 16 July 2024

<sup>&</sup>lt;sup>142</sup> Ministerial decision on the TRIPS Agreement (22nd June 2022) World Trade Organization. Available at: <a href="https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True">https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True</a> Accessed 16 July 2024

<sup>&</sup>lt;sup>143</sup> House of Commons Research Briefing, Loft (2022) Waiving intellectual property rights for Covid-19 vaccines. https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf Accessed 16 July 2024

<sup>144</sup> Médecins Sans Frontières (2022) Lack of a real IP waiver on COVID-19 tools is a disappointing failure for people. Available at: <a href="https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people">https://www.msf.org/lack-real-ip-waiver-covid-19-tools-disappointing-failure-people</a> Accessed 16 July 2024

<sup>145</sup> House of Commons Research Briefing (2024) What is the proposed WHO Pandemic Preparedness Treaty?.
Available at: <a href="https://commonslibrary.parliament.uk/research-briefings/cbp-9550/">https://commonslibrary.parliament.uk/research-briefings/cbp-9550/</a> Accessed 16 July 2024



#### H.9 Vaccine development market failure and filling the funding gap

Expertise and infrastructure for vaccine innovation is primarily concentrated in academic/government institutions and industry in HICs. Biomedical R&D requires effective coordination between these groups, with the private sector usually taking on the later stages of commercialisation and manufacturing, 146 However, several factors significantly reduce the financial incentive for companies to invest in vaccine development:

- EIDs arise sporadically and unpredictably, resulting in an unsustainable market for these products in the long term
- Most disease outbreaks occur in LMICs, which have a lower concentration of vaccine R&D capacity and expertise, as well as limited funding from national governments to support vaccine development and administration
- The highly challenging, lengthy, and costly nature of vaccine R&D, with the unpredictability of outbreaks introducing further risks to already lengthy clinical development timelines

To help alleviate these market challenges, international organisations such as Gavi, the Vaccine Alliance, undertake market shaping activities to stimulate industry investment in vaccine R&D (see section H.3). For example, Gavi's Vaccine Investment Strategy 2024 identifies emerging infectious diseases as a strategic priority and includes support for future vaccine rollout contingent on readiness, with a focus on partnership with CEPI for pathogens such as MERS, Nipah, and Lassa fever. 147 In addition, public funders and philanthropic organisations support vaccines R&D and capacity building along all stages of the vaccine development pipeline.

#### H.10 The vaccine R&D funding landscape

The G-FINDER database tracks R&D funding for new products and technologies that address global health challenges. 148 It includes information on R&D funding for all UKVN priority diseases except plague, Hantavirus disease, and Q Fever (which are hence not included in the figures reported below).149

From 2016 to 2023, G-FINDER reports shows £1.45 billion in vaccine R&D targeting UKVN priority pathogens for public and philanthropic funders, with public funding accounting for 98% of this figure. Funding levels for vaccines targeting Ebola and Zika were highest, especially over the 2016 to 2020 period (Figure 15), mirroring the outbreaks in West Africa and South America.

Vaccine R&D targeting Ebola virus received the largest amount of funding, £650 million (44.9% of vaccine R&D funding for UKVN priority pathogens for which G-FINDER holds information), followed by Zika virus (£397m, 27.5%) and Marburg virus (£161m, 11.2%). Funding for all other UKVN pathogens was less than 5%.

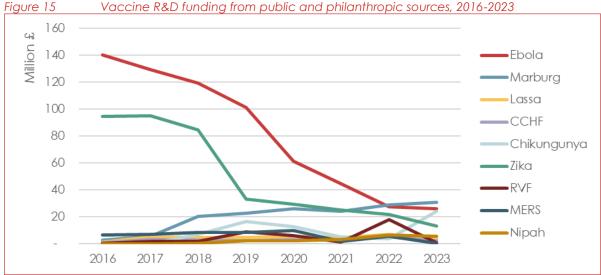
<sup>146</sup> Sanami et al (2017) Translating healthcare innovation from academia to industry. Advances in Mechanical Engineering. 9(3). https://doi.org/doi:10.1177/1687814017694114

<sup>&</sup>lt;sup>147</sup> Investment Strategy 2024, GAVI. https://www.gavi.org/our-alliance/strategy/vaccine-investment-strategy-2024

<sup>148 &</sup>lt;a href="https://afinderdata.policycuresresearch.org/">https://afinderdata.policycuresresearch.org/</a> Accessed 22 July 2025

<sup>&</sup>lt;sup>149</sup> G-FINDER reports on Ebola funding from 2014, on Marburg, CCHF, RVF, Lassa and Zika from 2015, on MERS, Nipah and Disease X from 2016, and on Chikungunya from 2018. To maximise comparability, this analysis focusses on 2016-2023 data for investment in vaccine R&D; however, funding for Chikungunya does not include 2016 and 2017 and is hence underreported. https://gfinderdata.policycuresresearch.org/assets/media/pdf/EID\_R&D\_scope.pdf.





Source: G-FINDER database. Note: 'Public funders' includes funding from Science & Technology agencies, other public government, aid agencies, and multilaterals.

Public funding from the United States accounted for the majority for UKVN pathogen vaccine R&D (£1.15bn, 79.6%), with most of this funding going towards vaccines targeting Ebola (44%), Zika (31%) and Marburg (14%) viruses (Figure 16). This is followed by contributions from the EU (£194.6m, 13.5%; mainly for Ebola, Chikungunya and RVF vaccines), the United Kingdom (£55.2m, 3.8%), South Korea (£14.1m, 1.0%), and Germany (£7.1m, 0.5%).

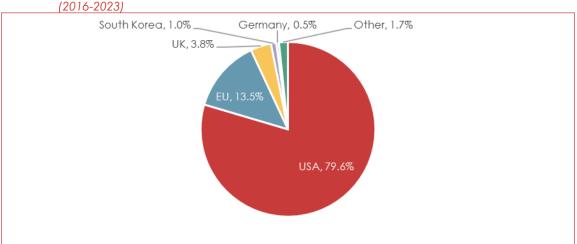


Figure 16 Public and philanthropic funding for vaccine R&D targeting UKVN pathogens, per country (2016-2023)

Source: G-FINDER database

Since 2017, G-FINDER also tracks data on funding for EID platform technology development (e.g. adjuvants and immunomodulators, general diagnostic platforms, and vaccine-related platform technologies), and for cross-cutting fundamental research on EIDs (e.g. understanding One Health approaches and animal-human disease epidemiology).

A total of £971 million was invested in EID platform technologies by public (£897m) and philanthropic (£74m) funders over the 2017-2023 period (industry reported only £19 million in funding). The level of funding increased slowly between 2017 and 2022, staying between £64 million and £161 million, before rising sharply to £339 million in 2023. Almost all of the funding



captured by G-FINDER was provided by the US (£963m, 99.2%), with most of the funding provided by the US DoD (£801m), followed by the Gates Foundation (£60m, starting investments in 2020). The UK and EU contributed £51m and £15m (5.3% and 1.5%, respectively).

Fundamental research was funded with £201 million from public (£185m) and philanthropic (£16m) funders over the 2017-2023 period. As for platform technologies, the US provided the majority of funding (£165m, 82.1%), with approx. half contributed by the US DoD and the US NIH, each. The UK provided £12 million (6.0%). Among philanthropic funders, Wellcome contributed £8 million, and the Gates Foundation £5.3 million.

#### H.11 Vaccine R&D funders and key initiatives

National governments and philanthropic organisations fund vaccine R&D either directly, or through global partnerships such as CEPI and Product Development Partnerships (PDPs). This section introduces the main organisations and agencies supporting vaccine-related R&D (Table 34, Table 35, Table 36, Table 37, and Table 38). Reflecting the high cost of vaccine research and the global nature of the threat of EIDs, funders frequently collaborate to jointly support R&D efforts.

#### H.11.1 Global partnerships

• The Coalition for Epidemic Preparedness Innovations (CEPI)

The Coalition for Epidemic Preparedness Innovations (CEPI) aims to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats, ensuring they are accessible to all who need them. Established in 2017 in the aftermath of the 2014–2015 Ebola outbreak in West Africa, it was formed to support the development of vaccines and other medical countermeasures that could improve preparedness against outbreaks of epidemic infectious diseases by fostering collaborations between public and private sectors and leveraging scientific advancements.<sup>150</sup>

CEPI's initial objective was to advance vaccine candidates to Phase II clinical trials. However, in response to the COVID-19 pandemic, CEPI expanded its remit to include late-stage clinical development and manufacturing, as well as support for clinical trial networks based in LMICs. <sup>151</sup> The coalition's priority pathogen list includes MERS-CoV, Nipah, Lassa Fever, Rift Valley Fever, Chikungunya, and Disease X.

By 2024, CEPI had received US\$2.6bn from donors, including 35 national governments, the European Commission, and more than ten philanthropic organisations such as the Gates Foundation and Wellcome.<sup>152</sup> CEPI's 2022-2026 strategic aims are based on a projection of US\$3.5bn of funding.<sup>153</sup> CEPI's portfolio included 43 vaccine candidates, with a total commitment of up to US\$2.25bn (Table 33). After COVID-19 and Betacoronaviruses more broadly, R&D related to Lassa had seen the highest level of funding (US\$119.4m), followed by

<sup>150</sup> Gouglas D et al (2019) CEPI: Driving Progress Toward Epidemic Preparedness and Response. Epidemiologic Reviews, 41, 28 - 33. https://doi.org/10.1093/epirev/mxz012

<sup>151</sup> CEPI 2022-2026 strategy. Available at: <a href="https://static.cepi.net/downloads/2023-12/CEPI-2022-2026-Strategy-v3-Jan21\_0.pdf">https://static.cepi.net/downloads/2023-12/CEPI-2022-2026-Strategy-v3-Jan21\_0.pdf</a> Accessed 21 June 2024

<sup>152</sup> CEPI 2023 investors overview. Available at: <a href="https://static.cepi.net/downloads/2024-01/2023\_12\_20-CEPI-Investors-Overview.pdf">https://static.cepi.net/downloads/2024-01/2023\_12\_20-CEPI-Investors-Overview.pdf</a> Accessed 16 July 2024

<sup>&</sup>lt;sup>153</sup> CEPI 2022-2026 strategy. Available at: <a href="https://static.cepi.net/downloads/2023-12/CEPI-2022-2026-Strategy-v3-jan21\_0.pdf">https://static.cepi.net/downloads/2023-12/CEPI-2022-2026-Strategy-v3-jan21\_0.pdf</a> Accessed 21 June 2024



Nipah, RVF and MERS (US\$70-90m each) and Chikungunya (US\$38.7m). For R&D related to epidemic preparedness more generally, Disease X, CEPI committed US\$283.6m.<sup>154</sup>

To support the development of a global manufacturing network and build technical expertise, CEPI collaborates with companies and research institutes in LMICs and engages LMIC experts in R&D projects. For example, CEPI's partnered with vaccine manufacturers Serum Institute of India to expand the company's capabilities, and with Indonesian manufacturer Bio Farma to develop and test mRNA and viral vector technologies and establish Good Manufacturing Practice (GMP)-standard facilities. 155,156

Table 33 CEPI portfolio, as of March 2024

Target disease Number vaccin candidates  COVID-19 7		R&D stage	Platform	Funding committed in US\$ (up to)	
		Phase I: 1 Registration: 6	Protein based: 1 RNA: 1 Viral vector: 5		
Betacorona (broadly protective)	8	Preclinical: 8	Protein based: 6 RNA: 2	143.4m	
Lassa	3	Preclinical: 1 Phase I: 1 Phase II: 1	Viral vector: 3	119.4m	
Nipah	3	Phase I: 3	Protein based: 1 Viral vector: 2	87.6m	
Rift Valley Fever	2	Preclinical: 1 Phase I:1	Live attenuated: 2	78.4m	
MERS	2	Phase I: 2	Viral Vector 2	70.8m	
Chikungunya	2	Phase IIb/III: 1 Registration: 1	Inactivated: 1 Live attenuated: 1	38.7m	
Disease X	16	Preclinical: 14 Phase I: 2	Protein based: 1 RNA: 14 Viral vector: 1	283.6m	
Total	43	Preclinical: 24 Phase I: 10 Phase II / Phase III: 2 Registration: 7	Protein based: 9 RNA: 17 Viral vector: 13 Attenuated/inactivated: 4	2.2 bn	

Source: Active CEPI-funded vaccine candidate portfolio by phase, CEPI. 157

The European Vaccines Initiative (EVI)

<sup>154</sup> Active CEPI-funded vaccine candidate portfolio by phase, March 2024. https://static.cepi.net/downloads/2024-04/CEPI%20active%20portfolio%20overview%20website Last%20Updated%204%20Apr%202024.pdf Accessed 5 Aug

<sup>155</sup> Serum Institute of India joins CEPI global network to boost production of affordable outbreak vaccines. CEPI.net. Available at: https://cepi.net/serum-institute-india-joins-cepi-global-network-boost-production-affordable-outbreakvaccines Accessed 25 June 2024

<sup>156</sup> CEPI and Bio Farma partnership boosts rapid response vaccine manufacturing for the Global South. CEPI.net. Available at: https://cepi.net/cepi-and-bio-farma-partnership-boosts-rapid-response-vaccine-manufacturingglobal-south Accessed 25 June 2024

<sup>157</sup> Active CEPI-funded vaccine candidate portfolio by phase, March 2024. https://static.cepi.net/downloads/2024-04/CEPI%20active%20portfolio%20overview%20website Last%20Updated%204%20Apr%202024.pdf Accessed 5 Aug 2024



The European Vaccines Initiative (EVI) is a PDP that supports global efforts to develop effective and affordable vaccines for diseases that disproportionately impact LMICs. <sup>158</sup> EVI coordinates translational research projects that progress early-stage vaccine candidates from discovery to early clinical trials.

EVI's current portfolio includes vaccine candidates against Nipah virus infection (preclinical stage, funded by the Japan's Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA)) and Zika virus disease (Phase I, funded by EU, in partnership with Themis Biosciences). 159 Other (non-UKVN) candidates in the EVI portfolio address malaria, Leishmaniasis and diarrheal diseases.

Over the 2016-2023 time period, EVI received funding for vaccine R&D targeting Zika, (£700,000) from the EU.<sup>160</sup>

EVI also works to harmonise processes for vaccine development and build capacity across Europe, as well as supporting capacity strengthening initiatives for vaccine R&D in LMICs.¹6¹ For example, the PDP coordinated the EU initiatives TRANSVAC (2009-2013, €11.9m) and its successor TRANSVAC2 (2017-2023, €14.6m), which aimed to accelerate the development of promising vaccine candidates by providing technical services and training courses, developing new technologies to address critical issues in vaccine R&D, and supporting cooperation between public vaccine R&D institutions, related initiatives and networks in Europe, and industrial partners (see EU section below).¹62,¹63

#### • The International AIDS Vaccine Initiative (IAVI)

The International AIDS Vaccine Initiative (IAVI) is a PDP founded in 1996 with the mission to develop a safe, affordable, globally accessible HIV vaccine. IAVI's remit has since expanded to include tuberculosis and EIDs, specifically COVID-19, Ebola Sudan virus, Lassa fever, and Marburg virus. The initiative receives funding from eight national governments as well as other funders including CEPI, the EU/EDCTP, and the BMGF.<sup>164</sup>

IAVI's EID vaccine candidates are based on a viral vector – the recombinant vesicular stomatitis virus (rVSV) vector – which is similar to the technology underlying Merck's Ebola Zaire virus vaccine ERVEBO®.165 The current pipeline includes candidates against Lassa fever (Phase II trial supported by CEPI, The European and Developing Countries Clinical Trials Partnership - EDCTP, and BARDA), Marburg virus (pre-clinical, supported by the US Department of Defense – DoD, and BARDA), and Ebola Sudan virus (Phase I, supported by BARDA).166 IAVI also undertakes epidemiological studies, such as a study on Lassa Fever incidence in Sierra Leone.167

<sup>158</sup> EVI, About us. Available at: <a href="https://www.euvaccine.eu/about-us">https://www.euvaccine.eu/about-us</a> Accessed 31 July 2024

<sup>&</sup>lt;sup>159</sup> EVI, Our portfolio. Available at: <a href="https://www.euvaccine.eu/portfolio">https://www.euvaccine.eu/portfolio</a> Accessed 31 July 2024

<sup>&</sup>lt;sup>160</sup> G-FINDER data portal on annual investment into R&D. Available at:

https://gfinderdata.policycuresresearch.org/pages/data-visualisations Accessed 22 July 2025

<sup>161</sup> EVI, Our Work. Available at: https://www.euvaccine.eu/our-work Accessed 30 July 2024

<sup>162</sup> CORDIS, TRANSVAC. Available at: https://cordis.europa.eu/project/id/228403/reporting/fr Accessed 31 July 2024

<sup>163</sup> TRANSVAC, About TRANSVAC. Available at: https://www.transvac.org/transvac2-about Accessed 31 July 2024

<sup>164</sup> IAVI. List of Funders. Available at: <a href="mailto:iavi.org/about-iavi/funders/">iavi.org/about-iavi/funders/</a> Accessed 30 July 2024

<sup>&</sup>lt;sup>165</sup> IAVI. EID Factsheet. Available at: <a href="https://www.iavi.org/wp-content/uploads/2023/10/iavi-fact-sheet-emerging-infectious-diseases-vaccines.pdf">https://www.iavi.org/wp-content/uploads/2023/10/iavi-fact-sheet-emerging-infectious-diseases-vaccines.pdf</a> Accessed 1 August 2024

<sup>166</sup> IAVI. Pipeline. Available at: https://www.iavi.org/our-work/emerging-infectious-diseases/ Accessed 26 July 2024

<sup>167</sup> IAVI. Our work, Epidemiology. Available at: https://www.iavi.org/our-work/epidemiology/ Accessed 1 August 2024



Over the 2016-2023 time period, IAVI received £29 million in funding for vaccine R&D targeting UKVN priority pathogens, mainly Marburg virus (£27m) with smaller amounts for Lassa, Nipah and MERS-CoV viruses.<sup>168</sup>

#### Gavi – the Vaccine Alliance

Gavi, the Vaccine Alliance, is a multilateral global health partnership with the mission to save lives and protect people's health by increasing the equitable and sustainable use of vaccines. <sup>169</sup> The alliance receives funding from 55 governments and the European Union, as well as 63 private and philanthropic foundations, corporations, institutions, and organisations. <sup>170</sup> Since its launch in 2000, Gavi has provided approximately US\$23bn to immunisation efforts in LMICs (excluding COVAX contributions), such as financial support for immunisation programmes, technical expertise, and market-shaping efforts such as AMCs and negotiating with manufacturers. <sup>171</sup> As of June 2024, Gavi supports the introduction of vaccines against 20 diseases, including one from the UKVN target list, Ebola Virus Disease. <sup>172</sup>

Gavi also provides funding for health systems and immunisation strengthening and for enhancing vaccine manufacturing capacity in LMICs, e.g. through the African Vaccine Manufacturing Accelerator (AVMA) (see section H.11.2).<sup>173</sup>

#### Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)

The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) is a network of global research funders aiming to improve preparedness and a rapid research response to epidemics by coordinating investments and through information sharing.<sup>174</sup> While not specifically focussed on vaccine R&D, GloPID-R drives forward the infrastructure and collaborative frameworks needed to respond quickly and effectively to outbreaks, including for vaccine R&D.

The collaboration has convened global funders to coordinate responses to COVID-19, Ebola, Zika, Chikungunya and Plague outbreaks in the past. In March 2024, GloPID-R launched Pandemic PACT, a programme to track and analyse global funding and evidence for a range of diseases alignment with the WHO priority diseases. 175 Other current GloPID-R projects include the development of a coordinated funding mechanism to invest in cross-cutting research focussed on clinical trials. 176 GloPID-R is also in the process of setting up regional hubs to help address outbreak preparedness and response challenges specific to each region, and to focus

<sup>168</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations
Accessed 22 July 2025

<sup>169</sup> Gavi, about our alliance. Available at: https://www.gavi.org/our-alliance/about Accessed 30 July 2024

<sup>170</sup> Gavi Donor Profiles. Available at: https://www.gavi.org/investing-gavi/funding/donor-profiles Accessed 30 July 24

<sup>171</sup> KFF (2024) The U.S. Government and Gavi, the Vaccine Alliance. Available at: https://www.kff.org/global-health-policy/fact-sheet/the-u-s-government-gavi-the-vaccine-alliance/

<sup>172</sup> Gavi Vaccine Investment Strategy (2024) Available at: <a href="https://www.gavi.org/programmes-impact/types-support/vaccine-support">https://www.gavi.org/programmes-impact/types-support/vaccine-support</a> Accessed 30 July 2024

<sup>173</sup> Gavi website, VaccinesWork. The African Vaccine Manufacturing Accelerator: what is it and why is it important https://www.Gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important Accessed 13 August 2024

<sup>174</sup> GLoPID-R website. Available at: https://www.glopid-r.org/ Accessed 13 August 2024

<sup>&</sup>lt;sup>175</sup> Pandemic Pact website. Available at: <a href="https://www.pandemicpact.org/">https://www.pandemicpact.org/</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>176</sup> GLoPID-R website, Clinical trial focus. Available at: <a href="https://www.glopid-r.org/clinical-trial-focus/">https://www.glopid-r.org/clinical-trial-focus/</a> Accessed 13 August 2024



on regional research priorities, capacity building and funder engagement. A total of four hubs are planned, with hubs in Africa and Asia Pacific already set up.

Table 34 Global partnerships relevant to vaccine R&D

Name	Mission	Total Funding Received	Target Diseases	Other Funding/Activities
Coalition for Epidemic Preparedness Innovations (CEPI)	Accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats, ensuring they are accessible to all who need them	US\$2.6bn from donors, including 35 national governments, EC, 10+ philanthropic organisations; projected US\$3.5bn (2022-2026)	MERS-COV, Nipah, Lassa Fever, Rift Valley Fever, Chikungunya, Disease X, COVID-19	Collaborations with institutes in LMICs and engagement of LMIC experts in R&D projects
European Vaccines Initiative (EVI)	Support global efforts to develop effective and affordable vaccines for diseases that disproportionately impact LMICs	Funding for Zika vaccine R&D: £0.7m Funding from SCARDA for pre- clinical Nipah virus vaccine R&D	Nipah virus, Zika virus; malaria, Leishmaniasis, diarrheal diseases, COVID- 19	Coordinated EU initiatives TRANSVAC (€11.9m) and TRANSVAC2 (€14.6m); capacity strengthening initiatives for vaccine R&D in LMICs
International AIDS Vaccine Initiative (IAVI)	Develop a safe, affordable, globally accessible HIV vaccine; expanded to include TB and EIDs	Funding for vaccine R&D for UKVN priority pathogens: £29m Includes £27m for Marburg virus	HIV/tuberculosis COVID-19/MERS, Ebola Sudan virus, Lassa fever, Marburg virus	Epidemiological studies, such as a study on Lassa Fever incidence in Sierra Leone
Gavi – the Vaccine Alliance	Save lives and protect people's health by increasing the equitable and sustainable use of vaccines	US\$23bn to immunisation efforts in LMICs since 2000 (excluding COVAX contributions)	Supports vaccines against 20 diseases, including Ebola Virus Disease.	Funding for health systems and immunisation strengthening; enhancing vaccine manufacturing capacity in LMICs via African Vaccine Manufacturing Accelerator (AVMA)
Global Research Collaboratio n for Infectious Disease Preparedness (GloPID-R)	Improve preparedness and a rapid research response to epidemics by coordinating investments and through information sharing	Coordination function, network of global research funders	Not specific to vaccines Supports infrastructure and collaborative frameworks needed to respond quickly and effectively to outbreaks	Pandemic PACT: tracks and analyse global funding and evidence for WHO priority diseases Development of a coordinated funding mechanism for clinical trials

Source: Technopolis analysis. For references on individual initiatives, see relevant sections above

#### H.11.2 National funders

### The United States of America (US)

 US National Institutes of Health (NIH) / National Institute of Allergy and Infectious Diseases (NIAID)

The National Institutes of Health (NIH) is the principal biomedical research agency in the US, focussed primarily on basic and early-stage research. Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID) leads on infectious disease research and emerging



public health threats in the US and globally. NIAID manages a diverse research portfolio with funding totalling US\$6.6bn in 2023.<sup>177</sup>

Vaccine R&D is a priority for NIAID, both through grant funding to research organisations, and through funding to the NIAID Vaccine Research Centre (VRC). NIAID supports research across the stages of vaccine development from basic immunology to clinical testing of candidate vaccines. Over the 2016-2023 timeframe, the G-FINDER database identifies nearly £470 million in NIH funding for vaccine R&D on UKVN priority pathogens, mainly for vaccine R&D targeting Ebola (£173m), Zika (£138m) and Marburg (£44m) viruses, but also for MERS, Lassa, and Chikungunya (£25-30m each) and Nipah, CCHF and RVF (£4.4-18m). 178

The NIAID priority pathogen list currently includes all pathogens targeted by the UKVN.<sup>179</sup> The agency also funds research on cross-cutting technologies, such as development of new vaccine platforms, vaccine manufacturing and human immunology.<sup>180</sup>

#### US Biomedical Advanced Research and Development Authority (BARDA)

The Biomedical Advanced Research and Development Authority (BARDA) supports the development of medical countermeasures against threats to public health, including EIDs, pandemic influenza, and antibiotic resistance. BARDA focusses on translational research and late-stage development of products, partnering with industry to bridge the gap between basic research and commercialisation.<sup>181</sup>

In line with its remit to protect the American public, the agency was the largest international funder of COVID-19 vaccine R&D, providing over US\$2.5bn from 2020-2022 according to G-FINDER. BARDA has also been supported vaccines R&D targeting UKVN priority pathogens with more funding than any other agency, providing £527.5 million across 2016-2023 for Ebola, Zika and Marburg virus.

#### US Department of Defense (DoD)

The US Department of Defense's (DoD) primary objective for investing in global health R&D is to protect US national security and US service members abroad. 183 The DoD hence focusses on R&D for products that work in low-resource or conflict settings and protect against infectious diseases that pose a risk to troops stationed abroad, as well as manmade and naturally occurring biological threats.

<sup>177</sup> NIAID Budget Data Comparisons, Available at: <a href="https://www.niaid.nih.gov/grants-contracts/niaid-budget-data-comparisons">https://www.niaid.nih.gov/grants-contracts/niaid-budget-data-comparisons</a> Accessed 13 August 2024

<sup>178</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations
Accessed 22 July 2025

<sup>&</sup>lt;sup>179</sup> NIAID Emerging Infectious Diseases/Pathogens | NIH: National Institute of Allergy and Infectious Diseases. Available at: <a href="https://www.niaid.nih.gov/research/niaid-biodefense-pathogens">https://www.niaid.nih.gov/research/niaid-biodefense-pathogens</a> Accessed 17 July 2024

<sup>180</sup> NIAID Vaccine Research Center's Key Disease Areas and Research Activities. Available at: <a href="https://www.niaid.nih.gov/about/vrc-key-disease-research-activities">https://www.niaid.nih.gov/about/vrc-key-disease-research-activities</a> Accessed 13 August 2024

<sup>181</sup> BARDA's Strategic Plan (2022-2026). Available at: <a href="https://www.medicalcountermeasures.gov/barda/strategic-plan/">https://www.medicalcountermeasures.gov/barda/strategic-plan/</a> Accessed 31 July 2024

<sup>182</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations Accessed 22 July 2025

<sup>183</sup> Global Health Technologies Coalition (2024) Doing well by doing good – the benefits of investing in global health R&D. Available at: <a href="https://www.ghtcoalition.org/resources-item/doing-well-by-doing-good-why-investing-in-global-health-r-d-benefits-the-united-states-and-the-world">https://www.ghtcoalition.org/resources-item/doing-well-by-doing-good-why-investing-in-global-health-r-d-benefits-the-united-states-and-the-world</a> Accessed 26 July 2024



DoD research activities span all areas of development, from basic research to late-stage development. <sup>184</sup> G-FINDER indicates that the department provided £142 million for vaccine-related R&D targeting UKVN priority pathogens, especially Ebola and Marburg (£64m each) and Lassa (£8.2m) (2016-2023). <sup>185</sup>

#### **European Union**

The European Union (EU) funds vaccine-related research and capacity building through a variety of mechanisms. Between 2016 and 2023, the G-FINDER database identifies around £195 million in funding towards vaccine R&D for UKVN priority diseases, with the majority committed to Ebola virus (£117m). $^{186}$ 

The EU funds a range of partnerships, projects and initiatives to support vaccines R&D and capacity building (see also Table 35):

The European and Developing countries Clinical Trials Partnership (EDCTP)

The European and Developing countries Clinical Trials Partnership (EDCTP) aims to accelerate the clinical development of new or improved health technologies, to detect, treat and prevent poverty-related and neglected infectious diseases prevalent in sub-Saharan Africa. The second phase of the partnership, EDCTP2, was announced in 2014 with a €683 million contribution from the EU (Horizon 2020) and around €1.5 billion from European countries. EDCTP3 was established in 2021 with a budget of €1.86bn.¹87 Funding is available for North-South and South-South collaborations.

The partnership's original focus on HIV/AIDS, malaria and tuberculosis was extended in EDCTP2 to include neglected and emerging infectious diseases, diarrhoeal diseases and lower respiratory tract infections. EDCTP3's scope was yet further extended to also include antimicrobial resistance and the impact of the climate crisis on infectious diseases. Photogramme focusses on all stages of clinical evaluation but particularly later-stage research (clinical trial phases III and IV).

<sup>&</sup>lt;sup>184</sup> Ratto-Kim et al (2018) The US Military Commitment to Vaccine Development: A Century of Successes and Challenges. Front Immunol. 9. <a href="https://doi.org/10.3389/fimmu.2018.01397">https://doi.org/10.3389/fimmu.2018.01397</a>

<sup>185</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations
Accessed 22 July 2025

<sup>&</sup>lt;sup>186</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations Accessed 22 July 2025

<sup>187</sup> GLOPID-R About Global Health EDCTP3 Joint Undertaking. Available at: <a href="https://www.glopid-r.org/members/global-health-edctp3-joint-undertaking">https://www.glopid-r.org/members/global-health-edctp3-joint-undertaking</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>188</sup> European Commission. Europe and Africa double research efforts to tackle AIDS, Ebola, and other infectious diseases. Available at: <a href="https://ec.europa.eu/commission/presscorner/detail/de/IP\_14\_2273">https://ec.europa.eu/commission/presscorner/detail/de/IP\_14\_2273</a> Accessed 13 August 2024

<sup>189</sup> Global Health European and Developing Countries Clinical Trials Partnership 3. About us. Available at: <a href="https://globalhealth-edctp3.eu/about-us/edctp2-global-health-edctp3">https://globalhealth-edctp3.eu/about-us/edctp2-global-health-edctp3</a> Accessed 13 August 2024



From 2014 to 2021, the EDCTP provided €243.05m in funding to 26 vaccine-related grants for collaborative clinical trials and clinical studies. 190 This included clinical trials for the development of vaccines against Ebola and Lassa virus. 191,192

In addition, the EDCTP supports strengthening of research capacity such as developing laboratory and clinical facilities. Current investments target training and development of African researchers, strengthening ethics and regulatory capacity for clinical research, and improving disease surveillance skills to better respond to emerging pathogens.<sup>193</sup>

#### TRANSVAC and ISIDORe projects

The EU-funded TRANSVAC project (2009-2013, €11.9m, FP7) and its successor TRANSVAC2 (2017-2023, €14.6m, Horizon2020) aimed to accelerate the development of promising vaccine candidates and enhance European vaccine R&D capacity and infrastructure. 194,195 The projects, coordinated by EVI, provided technical services and training courses, and developed new technologies to address critical issues in vaccine R&D. They also supported cooperation between public vaccine R&D institutions, related initiatives and networks in Europe, and industrial partners.

TRANSVAC2 served as a founding research infrastructure for the Integrated Services for Infectious Disease Outbreak Research (ISIDORe) project initiated in February 2022 with a budget of €21m.<sup>196</sup> ISIDORe aims to improve the EU's readiness to epidemic and pandemic threats by providing developers free-of-charge access to state-of-the-art facilities, services, equipment and technologies. It integrates a consortium of 154 research entities and organisations.<sup>197</sup>

Scientists working on pandemic preparedness for pathogens on ISIDORe's priority list can apply to access services. The list includes nine of the UKVN priority pathogens: Ebola, Marburg, Nipah, Lassa, CCHF, RVF, Zika, Chikungunya, and Disease X. 198

# • Innovative Medicines Initiative (IMI)

The Innovative Medicines Initiative (IMI) is a life sciences public-private partnership between the European Commission and the European pharmaceutical industry. IMI funds health research and innovation to develop next generation vaccines, medicines and treatments, aligned with European health priorities.<sup>199</sup>

<sup>190</sup> EDCTP's investment in research and development. (2014-2021) Interactive Portfolio. Available at: https://edctp.maglr.com/international-partnerships-against-infectious-diseases/edctp-s-investment-in-r-d 30 July 2024

<sup>&</sup>lt;sup>191</sup> Vaccine Research Institute, Trial on safety and immunogenicity of Ebola vaccines yields promising results. Available at: https://vaccine-research-institute.fr/ebola-vaccines-promising-results/ Accessed 13 August 2024

<sup>192</sup> IAVI led consortium receives EDCTP and CEPI funding for a large-scale clinical trial of Lassa fever vaccine candidate. Available at: <a href="https://www.edctp.org/news/iavi-led-consortium-receives-edctp-and-cepi-funding-for-a-large-scale-clinical-trial-of-lassa-fever-vaccine-candidate/">https://www.edctp.org/news/iavi-led-consortium-receives-edctp-and-cepi-funding-for-a-large-scale-clinical-trial-of-lassa-fever-vaccine-candidate/</a> Accessed 13 August 2024

<sup>193</sup> EDCTP3 Projects. Available at: https://globalhealth-edctp3.eu/projects Accessed 13 August 2024

<sup>194</sup> CORDIS, TRANSVAC. Available at: https://cordis.europa.eu/project/id/228403/reporting/fr Accessed 31 July 2024

<sup>&</sup>lt;sup>195</sup> TRANSVAC, About TRANSVAC. Available at: <a href="https://www.transvac.org/transvac2-about">https://www.transvac.org/transvac2-about</a> Accessed 31 July 2024

<sup>196</sup> Flanders Vaccine. TRANSVAC2 concludes: key achievements and new horizons. Available at: https://flandersvaccine.be/transavc2-concludes-key-achievements-and-new-horizons/
Accessed 13 August 2024

<sup>197</sup> ISIDORe Website. Available at: <a href="https://isidore-project.eu/about-us/#mission">https://isidore-project.eu/services/</a>/ Accessed 13 August 2024

<sup>198</sup> ISIDORe Website. Available at: <a href="https://isidore-project.eu/scientific-strategy/#ppps">https://isidore-project.eu/scientific-strategy/#ppps</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>199</sup> IMI Mission and objectives. Available at: <a href="https://www.imi.europa.eu/about-imi/mission-objectives">https://www.imi.europa.eu/about-imi/mission-objectives</a> Accessed 30 July 2024



The IMI has supported several vaccine-focussed consortia, including the Ebola+ programme, contributing to the development and approval of Johnson & Johnson's Ebola vaccine, and research to improve testing and monitoring of vaccine safety.<sup>200</sup>

 Team Europe initiatives – Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+)

Team Europe's Manufacturing and Access to Vaccines, Medicines and Health Technologies ('MAV+') initiative works with African partners to strengthen pharmaceutical systems and manufacturing capacity in Africa. MAV+ was announced in May 2021 with an initial budget of €1bn from the EU budget and European development finance institutions such as the European Investment Bank (EIB). An additional €600m from the EU and the Gates Foundation were made available in 2023.<sup>201</sup> Activities supported include development of training for a skilled workforce in the sector, strengthening the regulatory environment and supporting African research and technology transfer.<sup>202</sup>

African Vaccines Manufacturing Accelerator (AVMA)

In June 2024, the EU and Member States announced a contribution of over €750m to the African Vaccines Manufacturing Accelerator, a new financing mechanism for vaccine manufacture. AVMA's aim is to support the sustainable growth of Africa's vaccine manufacturing base and bring it closer to the goal of producing most vaccines required by African countries on the continent. It will offer incentive payments that offset some of the initial high costs of setting up vaccine production, focussing on vaccines against pathogens for which there is an unmet need (including only Ebola from the UKVN priority list) or for which a manufacturer establishes a prioritised vaccine technology platform in Africa that could be brought online during a pandemic response.

Table 35 EU initiatives and projects supporting vaccine R&D and capacity building

EU initiative or project	Aim	Stages funded	UKVN disease R&D funded	
European and Developing Countries Clinical Trials Partnership (EDCTP)	Accelerate clinical development of health technologies for poverty- related diseases in sub- Saharan Africa	€243.05m (2014-2021)	Late-stage (Phases III and IV)	Ebola, Lassa

<sup>&</sup>lt;sup>200</sup> Denoel, P et al (2018) Impact of the Innovative Medicines Initiative on vaccine development. Nat Rev Drug Discov. 17, 769–770. <a href="https://doi.org/10.1038/nrd.2018.72">https://doi.org/10.1038/nrd.2018.72</a>; <a href="https://www.ebovac.org/">https://doi.org/10.1038/nrd.2018.72</a>; <a href="https://www.ebovac.org/">https://doi.org/10.1038/nrd.2018.72</a>; <a href="https://www.ebovac.org/">https://www.ebovac.org/</a>

<sup>&</sup>lt;sup>201</sup> European Investment Bank. Global Gateway, EU steps up support for global health and equitable access to health products and local manufacturing. Available at: <a href="https://www.eib.org/en/press/all/2023-396-global-gateway-eu-steps-up-support-global-health-equitable-access-health-products-local-manufacturing">https://www.eib.org/en/press/all/2023-396-global-gateway-eu-steps-up-support-global-health-equitable-access-health-products-local-manufacturing</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>202</sup> European Commission. Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa. Available at: <a href="https://international-partnerships.ec.europa.eu/policies/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa\_en\_Accessed 13 August 2024</a>

<sup>&</sup>lt;sup>203</sup> European Commission, Press Release: Team Europe announces over €750 million to the African Vaccines Manufacturing Accelerator (20 July 2024) <a href="https://ec.europa.eu/commission/presscorner/detail/en/ip\_24\_3262">https://ec.europa.eu/commission/presscorner/detail/en/ip\_24\_3262</a> Accessed 31 July 2024

<sup>204</sup> Gavi website, VaccinesWork. The African Vaccine Manufacturing Accelerator: what is it and why is it important https://www.Gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important Accessed 13 August 2024



TRANSVAC and ISIDORe projects	Accelerate development of promising vaccine candidates and enhance European vaccine R&D capacity and infrastructure	€47.5m (2009-now)	All stages	Ebola, Marburg, Nipah, Lassa, CCHF, RVF, Zika, Chikungunya, Disease X
Innovative Medicines Initiative (IMI)	Develop next-generation vaccines, medicines, and treatments aligned with European health priorities	Not specified	All stages	Ebola
Team Europe initiatives – MAV+	Strengthen pharmaceutical systems and manufacturing capacity in Africa	€1.6bn	Capacity strengthening	
African Vaccines Manufacturing Accelerator (AVMA)	Support the sustainable growth of Africa's vaccine manufacturing base	€750m+	Capacity strengthening	Ebola, various other unmet need pathogens

Source: see relevant sections above

#### Germany

Federal Ministry of Education and Research (BMBF)

Germany's Federal Ministry of Education and Research (BMBF) allocates funding for research projects and institutions on behalf of the German Federal Government. The BMBF contributes to multiple international initiatives and PDPs that aim to improve equal access to safe and effective vaccines worldwide, including CEPI, Gavi, EDCTP, and the EVI.<sup>205</sup> For example, to date, Germany has provided €150 million for CEPI's core portfolio and an additional €430 million for COVID-19 vaccine R&D. The BMBF has pledged €40m for CEPI's core activities until 2026.<sup>206</sup>

While the BMBF has provided relatively little direct funding for UKVN priority targets, its contribution to COVID-19 vaccine R&D amounted to £1.05 billion, more than 20% of all R&D funding.<sup>207</sup> This included support for Germany's vaccine R&D capacity to accelerate the most promising vaccine candidates at companies such as BioNTech, CureVac, and IDT Biologika.<sup>208</sup> One of these grants was a commitment in September 2020 of up to €375m to BioNTech, supporting the development of their COVID-19 mRNA vaccine.<sup>209</sup>

#### **The United Kingdom**

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<sup>205</sup> GLOPID-R member page: BMBF. Available at: <a href="https://www.glopid-r.org/members/german-federal-ministry-of-education-and-research-bmbf-pt-dlr/">https://www.glopid-r.org/members/german-federal-ministry-of-education-and-research-bmbf-pt-dlr/</a> Accessed 31 July 2024

<sup>&</sup>lt;sup>206</sup> BMBF, Collaborations in Global Health. Available at: <a href="https://www.gesundheitsforschung-bmbf.de/en/coalition-for-epidemic-preparedness-innovations-cepi-8575.php">https://www.gesundheitsforschung-bmbf.de/en/coalition-for-epidemic-preparedness-innovations-cepi-8575.php</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>207</sup> G-FINDER data portal on annual investment into R&D. Available at: <a href="https://gfinderdata.policycuresresearch.org/pages/data-visualisations">https://gfinderdata.policycuresresearch.org/pages/data-visualisations</a> Accessed 24 June 2024

<sup>&</sup>lt;sup>208</sup> BMBF, Karliczek: Our funding paves the way for vaccine research against Covid-19. Available at: <a href="https://www.bmbf.de/bmbf/shareddocs/pressemitteilungen/de/karliczek-unsere-foerderung-eb-rschung-gegen-covid-19-den-weg.html">https://www.bmbf.de/bmbf/shareddocs/pressemitteilungen/de/karliczek-unsere-foerderung-eb-rschung-gegen-covid-19-den-weg.html</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>209</sup> BioNTech Press Release (2020) Available at: <a href="https://investors.biontech.de/news-releases/news-releas



Most public vaccine research funding within the UK is administered through UK Research and Innovation (UKRI) or the National Institute of Health and Care Research (NIHR) through competitive funding calls, with some block funding for research institutes.

G-FINDER records a total of £55 million in vaccine R&D funding for UKVN priority pathogens Ebola, CCHF, RVF, Chikungunya, Lassa, Nipah, MERS, and Marburg (2016-2023).<sup>210</sup>

The UKVN Project 1.0 received £110m of official development assistance (ODA) funding (2016 to 2022). Eight research competitions were designed between 2016 and 2021 which were delivered in partnership with the UKRI councils Innovate UK, BBSRC and EPSRC, and the NIHR.

### UK Research & Innovation (UKRI)

UK Research & Innovation (UKRI) is the umbrella organisation for the UK's research councils, Innovate UK, and Research England - including UKVN delivery partners EPSRC, BBSRC and Innovate UK. Innovate UK supports private sector-led innovation, with G-FINDER identifying £32 million in funding for UKVN priority diseases (2016-2023).

UKRI and its constituent councils contributed to a range of centres and hubs that conduct R&D relevant to vaccines and vaccine technologies. For example:

- In 2018, UKRI announced the Vaccine Manufacturing and Innovation Centre (VMIC) providing the UK vaccine industry with access to state-of-the art manufacturing facilities for vaccine R&D, and enable a rapid response to EID outbreaks.<sup>211</sup> Following additional investment after the start of the COVID-19 pandemic, bringing the total to nearly £200m, it was sold to a company in 2022.<sup>212</sup>
- The EPSRC has funded several R&D hubs focussed on vaccine manufacturing, such as two hubs funded through a UKVN 1.0 call
- Announced in 2023, the Centre for Veterinary Vaccine Innovation and Manufacturing (CVIM) aims to accelerate the development of animal vaccines to combat emerging and urgent infectious diseases.<sup>213</sup> This includes zoonotic diseases that could become a threat to public health in the UK and/or LMICs. CVIM projects will also cover the evaluation of novel manufacturing platforms, prioritising LMIC partners for technology transfer which can be implemented locally. The CVIM is funded by the BMGF (US\$20m), the UK Foreign Commonwealth Development Office (£10m) and the Biotechnology and Biological Sciences Research Council (BBSRC)(£8.5m).
- National Institute for Health and Care Research (NIHR)/ UK Department of Health and Social Care (DHSC)

The National Institute for Health and Care Research (NIHR) is funded by the UK Department of Health and Social Care (DHSC) to improve the health and wealth through research.<sup>214</sup>

<sup>&</sup>lt;sup>210</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations Accessed 22 July 2024

<sup>&</sup>lt;sup>211</sup> UKRI, UKRI funded vaccine development. Available at: <a href="https://www.ukri.org/who-we-are/how-we-are/doing/research-outcomes-and-impact/epsrc/ukri-funded-vaccine-development/">https://www.ukri.org/who-we-are/how-we-are/doing/research-outcomes-and-impact/epsrc/ukri-funded-vaccine-development/</a>. Accessed 13 August 2024

<sup>&</sup>lt;sup>212</sup> BBC News, Harwell VMIC: New vaccine centre sold to company. Available at: <a href="https://www.bbc.co.uk/news/uk-england-oxfordshire-61011189">https://www.bbc.co.uk/news/uk-england-oxfordshire-61011189</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>213</sup> The Pirbright Institute. Available at: <a href="https://www.pirbright.ac.uk/cvim">https://www.pirbright.ac.uk/cvim</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>214</sup> NIHR, Who we are. Available at: <a href="https://www.nihr.ac.uk/about-us/who-we-are/">https://www.nihr.ac.uk/about-us/who-we-are/</a> Accessed 13 August 2024



The NIHR's Global Health Research Portfolio was established in 2016. It supports applied health research for the direct and primary benefit of people LMICs, using UK international development funding, including to fund research in developing countries that are eligible to receive Official Development Assistance (ODA).<sup>215</sup>

Since 2021, the NIHR has funded 12 vaccine-related Global Health Research Units and Groups, some through the UKVN call for proposals, awarding just under £40m. This included a Phase I study of the viral vector ChAdOx1-MERS vaccine (Oxford University), trials of a vaccine candidate for RVF, ChAdOx1-GnGc for livestock and human vaccination (Pirbright Institute, Oxford University), as well as vaccine R&D addressing CCHF and Zika.<sup>216</sup>

The DHSC provides funds to the NIHR as well as to other funders, e.g. via the UKVN 1.0 and 2.0, and to CEPI. G-FINDER identifies £12 million in funding from the DHSC for UKVN priority diseases.

The UK Health Security Agency (UKHSA)

The UK Health Security Agency (UKHSA) is the UK government agency responsible for public health protection and infectious disease monitoring and protection capability. Vaccines form a central part of UKHSA's 2023 Science Strategy.<sup>217</sup>

In 2022, UKHSA announced a ten-year strategic partnership with Moderna, including building of a UK manufacturing facility, investment in mRNA R&D, and measures to enhance scale up capabilities in the event of a future pandemic.<sup>218</sup>

In 2023, UKHSA established the Vaccine Development and Evaluation Centre (VDEC), which aims to facilitate the development and evaluation of new vaccines and therapeutics against pathogens of pandemic potential, high-consequence infectious diseases and high-risk infectious diseases potential.<sup>219</sup> VDEC offers facilities and capabilities (including biosafety level 2, 3, and 4) to support vaccine developers from across sectors. It has international partners, e.g. BARDA and CEPI.

#### Japan

 Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA)

Japan is a relative newcomer in the vaccine R&D space. After decades of low R&D activity relevant to vaccines, the COVID-19 pandemic led the Japanese government to take action. The Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA) was established in March 2022, as part of the Japanese government's "National Strategy for Strengthening the Vaccine Development and Production

<sup>&</sup>lt;sup>215</sup> NIHR, Global health research. Available at: <a href="https://www.nihr.ac.uk/explore-nihr/funding-programmes/global-health.htm">https://www.nihr.ac.uk/explore-nihr/funding-programmes/global-health.htm</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>216</sup> NIHR Awards and outputs, search for 'Vaccines'. Available at: <a href="https://fundingawards.nihr.ac.uk/?query=vaccine">https://fundingawards.nihr.ac.uk/?query=vaccine</a> Accessed 13 August 2024

<sup>217</sup> UKHSA Science Strategy (2023). Available at: <a href="https://ukhsa.blog.gov.uk/2023/05/16/ukhsa-science-strategy-a-vision-for-how-science-can-secure-health-and-prosperity/">https://ukhsa.blog.gov.uk/2023/05/16/ukhsa-science-strategy-a-vision-for-how-science-can-secure-health-and-prosperity/</a> Accessed 31 July 2024

<sup>&</sup>lt;sup>218</sup> GOV.UK. The 100 Days Mission: how the UK is contributing of the global mission to develop pandemic-fighting tools within 100 days. Available at: <a href="https://www.gov.uk/government/publications/100-days-mission-uk-specific-report-for-2022/100dm-how-the-uk-is-contributing-to-the-global-mission-to-develop-pandemic-fighting-tools-within-100-days Accessed 13 August 2024</a>

<sup>&</sup>lt;sup>219</sup> UKHSA Vaccine Development and Evaluation Centre. Available at: <a href="https://www.gov.uk/government/news/ukhsa-unveils-vdec-in-step-change-for-uks-growing-vaccine-capabilities">https://www.gov.uk/government/news/ukhsa-unveils-vdec-in-step-change-for-uks-growing-vaccine-capabilities</a> Accessed 31 July 2024



System," with the aim of enhancing the country's preparedness and response for future pandemics.

An article by Science reports that the Japanese government allocated a budget of US\$8.5bn for vaccine R&D (2022-2027), with SCARDA providing US\$400 million to new vaccine R&D centres at several universities, and other agencies providing US\$2.7bn to vaccine-related startup companies, US\$1.7bn for improving vaccine manufacturing, and US\$2bn to support large clinical trials and purchase COVID-19 vaccines.<sup>220</sup>

SCARDA's strategy was developed from the lessons of the COVID-19 pandemic, which had highlighted Japan's weaknesses in vaccine R&D. SCARDA's strategy recognises the lack of human and financial resources in vaccine development in Japan. To address these issues, SCARDA funds two primary funding programs: a) the development of vaccines and new modalities up to Phase II clinical trials, and b) infectious disease and vaccine research in academia and institutions contributing to vaccine development.

Publications from projects funded by SCARDA include work on COVID-19, MERS and Nipah, and the agency is funding the EVI to progress the development of a Nipah vaccine (US\$15m).<sup>221,222</sup> SCARDA has also signed a Memorandum of Cooperation to collaborate with CEPI.<sup>223</sup>

A summary of public funders supporting vaccine R&D and capacity building is provided in Table 36.

Table 36 Public funders of vaccine / vaccine technology R&D and capacity building

Country	Funder	Aim	Funding for vaccines	Stages funded	UKVN disease R&D funded
United States	National Institutes of Health (NIH) / NIAID	Biomedical research on basic and early-stage infectious disease research and emerging public health threats	UKVN priority pathogens: £468m (2016-2023)	Discovery to clinical testing	Ebola, Zika, Marburg, Lassa, Chikungunya,
	US Biomedical Advanced Research and Development Authority (BARDA)	Development of medical countermeasures against public health threats	UKVN priority pathogens: £528m (2016-2023) +U\$\$2.5bn for COVID-19 (2020-2022)	Focus on translational, late-stage	Ebola, Marburg, Zika COVID-19
	US Department of Defense (DoD)	Protecting US national security and service members through R&D for products in low-resource or conflict settings	UKVN priority pathogens: £142.1m (2016-2023)	All stages	Ebola, Marburg, Lassa

<sup>220</sup> Science.org, Japan moves to bolster vaccine R&D after COVID-19 exposed startling wekness. Available at: <a href="https://www.science.org/content/article/japan-moves-bolster-vaccine-r-d-after-covid-19-exposed-startling-weakness">https://www.science.org/content/article/japan-moves-bolster-vaccine-r-d-after-covid-19-exposed-startling-weakness</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>221</sup> ePMC search for 'SCARDA'; a definitive list of priority pathogens could not be located

<sup>&</sup>lt;sup>222</sup> EVI, SCARDA MV-Nipah. Available at: <a href="https://www.euvaccine.eu/emerging-diseases/scarda-mv-nipah">https://www.euvaccine.eu/emerging-diseases/scarda-mv-nipah</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>223</sup> Japan AMED. SCARDA and CEPI collaborate to strengthen global pandemic preparedness and response. Available at: <a href="https://www.amed.go.jp/en/news/release-20230626.html">https://www.amed.go.jp/en/news/release-20230626.html</a> Accessed 13 August 2024



European Union	European Union (EU)	Vaccine-related research and capacity building through various mechanisms	UKVN priority pathogens: £195m (2016-2023)	All stages	Ebola, COVID-19, platform technologies
Germany	Federal Ministry of Education and Research (BMBF)	Funding research projects and institutions to improve equal access to safe and effective vaccines worldwide	€580m	All stages	Zika, Ebola, Marburg, COVID- 19
United Kingdom	UK Research & Innovation (UKRI)	Supporting innovation through funding calls and block funding for research institutes	UKVN priority pathogens: £32m (2016-2023)	All stages	Ebola, CCHF, Chikungunya, Lassa, Nipah, MERS, RVF, Marburg
	National Institute for Health and Care Research (NIHR)	Applied health research for the benefit of people in LMICs using UK international development funding	£40m (since 2021)		MERS, RVF, CCHF, Zika
	UK Department for Health and Social Care (DHSC)	Global Health Security, including UKVN 1.0 and 2.0 and other programmes	More than £1b (2016 to date)		Various pathogens of pandemic potential
	UK Health Security Agency (UKHSA)	Public health protection and infectious disease monitoring and protection capability	Not specified		Various pathogens of pandemic potential
Japan	SCARDA	Enhancing preparedness and response for future pandemics by funding vaccine development and research	U\$\$8.5bn (2022-2027)	Up to Phase	COVID-19, MERS, Nipah

Source: see relevant sections above

### Philanthropic organisations

The Bill and Melinda Gates Foundation (BMGF)

The Bill and Melinda Gates Foundation (BMGF), one of the largest private charitable organisations, provides funding to support global development. One of its seven priority areas is Global Health. The BMGF Vaccine Development and Surveillance portfolio includes investments to develop technical expertise and novel platforms for clinical evaluation, vaccine manufacturing, quality control, surveillance and epidemiology, aiming 'to make vaccines faster, better, and cheaper, including in low-resource settings'.<sup>224</sup>

The BMGF does not specifically targeted any UKVN-priority diseases, but provided funding to industry for Ebola vaccine R&D in 2014 (US\$2.5m) and to a range of R&D organisations for COVID-19 vaccine R&D in 2020-2022 (US\$166.5m, e.g. US\$53.1m to industry and US\$22.6m to

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<sup>224</sup> BMGF Areas of Focus: Vaccine development and surveillance. Available at: https://www.gatesfoundation.org/our-work/programs/global-health/vaccine-development-and-surveillance Accessed 30 July 2024



CEPI).<sup>225</sup> The foundation emphasises a cross-disease area approach, supporting vaccine technology innovation. One example is a US\$40m grant for the development of mRNA vaccine manufacturing technology accessible for developing country manufacturers and its transfer to manufacturers in South Africa and Senegal.<sup>226</sup> Another area of support is for the development of vaccine microarray patches (see H.2), including for delivery of mRNA-based vaccines.<sup>227</sup>

The BMGF also supports capacity strengthening in LMICs, e.g. through the Team Europe Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+), to which it contributed US\$600m (see above).

### • The Wellcome Trust (Wellcome)

The Wellcome Trust is an independent charitable foundation with the mission to solve the urgent health challenges through support for research and advocacy. Wellcome intends to invest £16bn from 2022 to 2032, maintaining their support for discovery science while also focussing on three global health challenges: climate change and health, mental health, and infectious diseases. 229

Within the infectious diseases theme, Wellcome funds researchers directly through grants, and provides funding to intermediaries such as CEPI (e.g. for Ebola R&D) and IAVI (Lassa vaccine development, see above).<sup>230</sup> According to G-FINDER, Wellcome supported vaccine R&D targeting Ebola with a total of £12 million over the 2016-2023 time period, and R&D targeting Lassa virus with a total of £600,000 in 2020-2022.

Wellcome also supports the vaccine R&D ecosystem more broadly. For example, in 2020, Wellcome published a report identifying barriers to vaccine development and drivers of clinical development decisions at each stage.<sup>231</sup> To address one of these barriers - the high cost and time required for clinical trials especially for diseases with unpredictable incidence -, Wellcome and CEPI co-funded a 2024 call for proposals to identify correlates of protection (alternative efficacy measures that can reduce the time and cost of vaccine development).<sup>232</sup>

In addition, Wellcome supports R&D to improve epidemic preparedness in LMICs. For example, the trust co-funded the Joint Initiative on Research in Epidemic Preparedness and Response (JIREP) with the UK Foreign, Commonwealth and Development Office (FCDO) from 2018 to

<sup>225</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations Accessed 24 June 2024

Pharmaceutical Technology, Gates Foundation announces \$40m for mRNA vaccine platform.
<a href="https://www.pharmaceutical-technology.com/news/gates-foundation-mrna-vaccine-platform/">https://www.pharmaceutical-technology.com/news/gates-foundation-mrna-vaccine-platform/</a> Accessed 13 August 2024

<sup>227</sup> BMGF, Committed grants. Available at: <a href="https://www.gatesfoundation.org/about/committed-grants">https://www.gatesfoundation.org/about/committed-grants</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>228</sup> The Wellcome Trust, Investments. Available at: <a href="https://wellcome.org/who-we-are/investments">https://wellcome.org/who-we-are/investments</a> Accessed 30 July 2024

<sup>&</sup>lt;sup>229</sup> Wellcome Annual Report (2023). Available at: <a href="https://wellcome.org/reports/wellcome-annual-report">https://wellcome.org/reports/wellcome-annual-report</a> Accessed 30 July 2024

<sup>&</sup>lt;sup>230</sup> G-FINDER data portal on annual investment into R&D. Available at: https://gfinderdata.policycuresresearch.org/pages/data-visualisations
Accessed 22 July 2025

<sup>&</sup>lt;sup>231</sup> Wellcome, Effective Vaccine Ecosystem. Available at: <a href="https://wellcome.org/sites/default/files/2021-10/effective-vaccine-ecosystem-equipped-to-meet-challenges-of-future-infectious-disease-threats.pdf">https://wellcome.org/sites/default/files/2021-10/effective-vaccine-ecosystem-equipped-to-meet-challenges-of-future-infectious-disease-threats.pdf</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>232</sup> Wellcome, Seeking predictors of vaccine efficacy: identifying correlates of protection to support vaccine development. Available at: <a href="https://wellcome.org/grant-funding/schemes/correlates-protection-for-vaccine-development">https://wellcome.org/grant-funding/schemes/correlates-protection-for-vaccine-development</a> Accessed 13 August 2024



2023.<sup>233</sup> The initiative included R&D in areas such as global health policy, health systems, public health, and social sciences relevant to outbreaks and outbreak recovery, including projects on the Ebola and Zika outbreaks.

A summary of public funders supporting vaccine R&D and capacity building is provided in Table 37.

Table 37 Philanthropic funders of vaccine / vaccine technology R&D and capacity building

Funder	Aim	Funding for vaccines	Stages funded	UKVN disease R&D funded
Bill and Melinda Gates Foundation (BMGF)	Supporting global health with a focus on faster, better, and cheaper vaccines in low- resource settings	US\$206m (2014-now)	All stages	Ebola, COVID-19, various cross- disease technologies/capacity building
Wellcome Trust	Solving urgent health challenges through support for research and advocacy, with a focus on infectious diseases, climate change, and mental health	US\$18m (2014- 2022)	All stages	Ebola, Lassa, various epidemic preparedness projects

#### H.11.2.1 Private sector activity in vaccine production and vaccines R&D

The global vaccines market is highly concentrated: Ten companies produce 75% of vaccine doses (excluding COVID-19 vaccines) and capture 85% of the global value of vaccines, with four companies (Merck/MSD, GSK, Pfizer and Sanofi) accounting for 15-24% each.<sup>234</sup> The remaining market is shared between 80 companies. Of the top ten vaccine manufacturers by volume produced, three are located in India (Bharat Biotech, Serum Institute, Biological E Ltd), one in China (China National Biotec Group), and six in the US and Europe (GSK, Sanofi, Pfizer, J&J, AZ, Moderna).

A 2023 market analysis identified that pharma companies were developing 1,300 vaccine candidates for around 150 diseases, with GSK's pipeline being the largest (38 vaccines candidates), followed by Moderna (33), Chongqing Zhifei Biological (29), Sanofi (26) and Pfizer (26).<sup>235</sup> Over half of all vaccine candidates targeted cancer (23%), coronavirus (23%), or influenza (8%), followed by candidates for pneumococcal disease, RSV, HPV, and HIV. While large US- and EU-based companies pursue mainly vaccines against cancer, coronavirus, and influenza, SMEs and companies in India and China are more strongly represented among developers of vaccines targeting a broad range of infectious diseases.<sup>236</sup>

G-FINDER identifies nearly £500 million in private sector investment for vaccine R&D targeting UKVN priority diseases from 2016 to 2023, with most funding going towards Ebola virus (£388m)

<sup>233</sup> Wellcome, How can we prevent epidemics? This initiative aims to find out. Available at:
<a href="https://wellcome.org/news/joint-initiative-research-epidemic-preparedness-and-response-how-it-works">https://wellcome.org/news/joint-initiative-research-epidemic-preparedness-and-response-how-it-works</a> Accessed 13 August 2024

<sup>&</sup>lt;sup>234</sup> World Health Organisation (2023) WHO Global Vaccine Market Report 2023. Available at: <a href="https://www.who.int/publications/i/item/B09022">https://www.who.int/publications/i/item/B09022</a> Accessed 16 July 2024

<sup>235</sup> Syneos Health Insights Hub (2023) Vaccine Innovation Trends Report: Global Vaccine R&D Pipeline and Delivery Implications. Available at: <a href="https://www.syneoshealth.com/insights-hub/vaccine-innovation-trends-report-global-vaccine-research-and-development-pipeline-and">https://www.syneoshealth.com/insights-hub/vaccine-innovation-trends-report-global-vaccine-research-and-development-pipeline-and</a> (page 13) Accessed 16 July 2024

<sup>&</sup>lt;sup>236</sup> Syneos Health Insights Hub (2023) Vaccine Innovation Trends Report: Global Vaccine R&D Pipeline and Delivery Implications. Available at: <a href="https://www.syneoshealth.com/insights-hub/vaccine-innovation-trends-report-global-vaccine-research-and-development-pipeline-and">https://www.syneoshealth.com/insights-hub/vaccine-innovation-trends-report-global-vaccine-research-and-development-pipeline-and</a> (page 14) Accessed 16 July 2024



and Zika (£61m), responding to the respective outbreaks. In addition to direct funding for vaccine R&D, mechanisms by which companies can be incentivised include market-shaping activities such as APCs or AMCs (as discussed in section H.3).

Venture capital investment for infectious disease vaccine R&D is much lower than in other health areas. Only 3.4% (\$6.5bn) of total venture capital raised globally by biopharmaceutical companies from 2013 to 2022 went to companies with vaccine programmes targeting infectious diseases, compared to 38% (\$72.6bn) invested in companies developing oncology drugs.<sup>237</sup>

Approved vaccines (5) and the current pipeline of vaccine candidates in clinical trials (28) targeting seven UKVN priority pathogens includes a total of 18 companies (Table 38).

Table 38 Companies involved in UKVN priority pathogen vaccine R&D, April 2025

Pathogen	No. of companies with current pipeline / approved vaccines	Companies involved in R&D
Ebola	7 (incl. 3 approved and 1 transferred)	Auro Vaccines, Novavax/US Army, Inovio, GSK (transferred to NIAID) [Merck, Janssen, CanSinoBio - approved]
Lassa	3	Emergent Biosolutions, Themis/Merck, Inovio (discontinued)
Chikungunya	8 (incl. 2 approved)	Moderna, Bharat Biotech, Human Biologicals Institute, Najit Technologies, Imutex/ConserV, Themis/Merck (discontinued) [Valneva, Bavarian Nordic - approved]
Zika	10	Valneva, Takeda, Inovio, Moderna, Themis Biosciences, Janssen, Bharat Biotech, Imutex/ConserV
MERS	1	Inovio (discontinued)
Nipah	2	Public Health Vaccines LLC, Auro Vaccines
Plague	2	Dynavax/US DoD, Lanzhou Institute of Biological Products Company

Source: WHO International Clinical Trials Registry Platform (ICTRP) Search Portal.<sup>238</sup>

<sup>237</sup> Thomas & Wessel (2023) The State of Innovation in Vaccines and Prophylactic Antibodies for Infectious Diseases.

Bio Industry Analysis for the Biotechnology Innovation Organization (BIO). Available at: <a href="https://www.bio.org/sites/default/files/2024-01/The-State-of-Innovation-in-Vaccines-and-Prophylactic-Antibodies-for-Infectious-Diseases.pdf">https://www.bio.org/sites/default/files/2024-01/The-State-of-Innovation-in-Vaccines-and-Prophylactic-Antibodies-for-Infectious-Diseases.pdf</a> Accessed 16 July 2024

<sup>&</sup>lt;sup>238</sup> WHO International Clinical Trials Registry Platform (ICTRP). Available at: <a href="https://trialsearch.who.int/">https://trialsearch.who.int/</a> Accessed May 2025



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