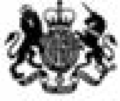

Department of Health & Social Care

Business Case Summary Sheet

Title: Fleming Fund		
Project Purpose: To tackle the deadly global impact of antimicrobial resistance (AMR) by improving laboratory capacity, diagnosis and building sustainable surveillance systems in Official Development Assistance (ODA) eligible countries, taking a One Health approach. This will be delivered through a portfolio of country, regional and global grants as well as individual fellowships in up to 25 countries across Sub-Saharan Africa, South and South-East Asia.		
Programme Value: Up to a maximum of £250m of ODA over four years (committed). This includes: Up to a maximum of £210m of ODA over three years 22/23-24/25 (permission to spend) Up to a maximum of £40m of ODA to be committed at risk in 25/26 (additional IC approval will be sought ahead of actual spend)		Country/ Region: Sub-Saharan Africa, South and South-East Asia.
Project Code:	Start Date: March 2022	End Date: March 2026
Overall programme risk rating:		
SharePoint link:		

Version	Lead	Date	Notes
1	[redacted]	7 December 2021	

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2	[redacted]	10 January 2022	
3	[redacted]	26 January 2022	

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Acronyms

AMC: Antimicrobial Consumption
AMR: Antimicrobial Resistance
AMU: Antimicrobial Use
APHA: Animal and Plant Health Agency
BATNA: Best Alternative to a Negotiated Agreement
BCR: Benefit-Cost Ratio
BEIS: Department for Business, Energy, and Industrial Strategy
CC: Coordination Committees
CDEL: Capital Departmental Expenditure Limits
Cefas: Centre for Environment, Fisheries and Aquaculture Science
CSF: Critical Success Factor
CWPAMS: Commonwealth Partnership for Anti-Microbial Stewardship
CIA: Comprehensive Investment Appraisal
Defra: Department for Environment, Food and Rural Affairs
DHSC: Department of Health and Social Care
EDI: Equality, Diversity, and Inclusion
EQ: Evaluation Questions
FAO: Food and Agriculture Organisation
FCDO: Foreign, Commonwealth and Development Office
FF: Fleming Fund
FRA: Fraud Risk Assessment
GDP: Gross Domestic Product
GGIS: Government Grants Information System
GHS: Global Health Security
GLASS: Global Antimicrobial Resistance and Use Surveillance System
GNI: Gross National Income
GRAM: Global Research on Antimicrobial Resistance
HCAI: Healthcare Associated Infections
HIV: Human Immunodeficiency Virus
HMG: Her Majesty's Government
HSS: Health Systems
IACG: Inter-Agency Coordination Group
ICAI: Independent Commission for Aid Impact
IDC: Indirect Costs
IDS: Acquired Immune Deficiency Syndrome
IHME: Institute of Health Metrics and Evaluation
IHR: International Health Regulations
IPA: International Procurement Agency
ITAI: International Aid Transparency Index
KPI: Key Performance Indicator
LMICs: Low-and-Middle-Income Countries
LSHTM: London School of Hygiene and Tropical Medicine
MA: Management Agent
MEL: Monitoring, Evaluating and Learning
MM: Mott Macdonald
M&OH: Management and Overhead Costs
MoU: Memorandum of Understanding
MPTF: Multi-Partner Trust Fund
NAP: National Action Plan
NGO: Nongovernmental Organisation
ODA: Official Development Assistance
ODI: Overseas Development Institute
OECD: Organisation for Economic Cooperation and Development
OECD DAC: OECD Development Assistance Committee
OIE: World Animal Health Organisation
OJEU: Official Journal of the European Union
PD: Programme Director
PHDA: Partners for Health and Development in Africa
PHE: Public Health England
PM: Programme Manager
PSED: Public Sector Equality Duty
PSM: Procurement and Supply Chain Management
RDEL: Resource Departmental Expenditure Limits
RFM: Regional Finance Manager
ROI: Return on Investment
SCS: Senior Civil Servant
SDG: Sustainable Development Goal
SF: Substandard and Falsified
SLA: Service Level Agreement
SO: Spending Objectives
SR: Spending Review
SRO: Senior Responsible Officer
SWOT: Strengths, Weaknesses, Opportunities, Threats
TAG: Technical Advisory Group
ToC: Theory of Change
TB: Tuberculosis
UKFM: UK based Financial Manager
UN: United Nations
UNDP: United Nations Development Programme
VfM: Value for Money
VMD: Veterinary Medicines Directorate
WHO: World Health Organization
WHO CC: World Health Organization Collaborating Centre

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Annex Log

A	Alignment with strategies
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R	Management agent technical appraisal process
S	Fleming Fund Project Board Terms of Reference
T	DHSC Global Health Security Programme Board Terms of Reference
U	DHSC ODA governance structure
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W	Fleming Fund Communications Strategy
X	Fleming Fund Stakeholder Mapping exercise
Y	Fleming Fund Coordination and Engagement plan
Z	MA accountability and leadership structure, roles and responsibilities for key personnel and MM management team responsibilities
AA	Management Agent sequence of procurement and supply-chain management principles
AB	Adaptive Management approach

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Summary of Intervention

In the 2021 Spending Review, DHSC was allocated £832m of Official Development Assistance (ODA) funding spread across all ODA programmes. Of this, the Fleming Fund has been allocated an indicative budget of £193.5m ODA over the next three years from 2022/2023 through to 2024/2025.

The Fleming Fund is seeking approval to commit up to a maximum of **£250m of ODA over four years**. This includes:

- a maximum of **£210m over 22/23-24/25,** with hard approval sought for £193.5m and provisional approval for the remaining £16.5m if required, and as long as this remains affordable within the overall GHS ODA three-year Spending Review allocation.
- **up to £40m committed at risk in year 4 (25/26)** in lieu of Spending Review funding being confirmed, as long as this remains affordable within the overall threshold approved for GHS to pre-commit funding in outer years. This is under the condition that **the Fleming Fund will include a clear break clause in the Management Agent contract at the end of year 3** (March 2025) to ensure DHSC can exit the contract at that point if needed. **The Fleming Fund will then revert to the Investment Committee in year 3 for approval to spend the funds committed in year 4 (25/26).**

Proposed indicative figures are set out below:

Headline figures (in £m)	22/23 **(£61m)**	23/24 **(£62.5m)**	24/25 **(£70m)**	25/26 **(£40m)**
RDEL				
Strengthening national surveillance – 76%-79%	41.04	43.85	48.51	30.00
AMR workforce capacity – 9-10%	5.40	4.99	6.30	1.80
Mobilising consensus on AMR – 5-7%	3.78	2.78	3.78	1.00
Analysing and using quality data – 6%	3.24	3.33	3.78	1.80
Monitoring, evaluation, and learning – 1%	0.54	0.55	0.63	0.40
RDEL Total	54.00	55.50	63.00	35.00
CDEL Total	7.00	7.00	7.00	5.00

Strategic case

This section makes the case for change by outlining the broader context of anti-microbial resistance (AMR) and the progress of the Fleming Fund to-date, explaining why changes in the operating environment since the programme started in 2016 have amplified the need for action. It then outlines the focus for phase II and the Fleming Fund's aim to ensure quality data is collected and used by policy makers.

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Economic case

This section outlines the strong economic case for AMR interventions including the new data that has emerged since the first business case and an overall value for money assessment. It includes an appraisal of intervention options, which has been monetised using a Comprehensive Investment Appraisal model.

Commercial Case

This section outlines the commercial approach to delivering the interventions laid out. It sets out the plan to renegotiate the contract with the Fleming Fund's Management Agent including outlining a focus on outcomes and considerations for the Fellowships element of the contract and value for money. It also outlines the Fleming Fund's intention to extend or renew existing contracts/ grant agreements provided they are in line with the strategic objectives and financial arrangements set out in this business case.

Financial case

This section outlines the budget, spend profile, monitoring, and operation of financial disbursements for the programme and how this will be managed to ensure the programme is delivered affordably and offers value for money. It also outlines how the Fleming Fund will meet ODA reporting requirements.

Management Case

This section outlines the structures in place to deliver this programme of activity. It sets out the approach to performance management of the Management Agent, Independent Evaluator, and grantees to ensure that they are delivering to the required quality, time, and budget. It also outlines the approach to Monitoring, Evaluation and Learning.

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Strategic Case

1. Overview

1.1 Building on the success of the first phase of the Fleming Fund and the ongoing need to tackle antimicrobial resistance (AMR) globally, this Strategic Case sets out the justification for building on the successes of this programme to support the Fleming Fund. Real impacts of phase I include supporting low- and middle-income countries (LMICs) to develop and sustain national programmes for surveillance of AMR and antimicrobial use (AMU). As set out below, this programme is an integral part of the UK's commitment to global health security. It delivers on national and international commitments to address AMR as a critical component of strengthening health systems (HSS) in LMICs.

2. The Context

2.1 The current COVID-19 pandemic has brought into sharp focus the importance, for all countries, of well-functioning health systems and strong surveillance systems. This includes capacity for infectious disease diagnosis and treatment; capacity for the management of severe infectious disease including intensive care; and the capacity and flexibility to detect and contain disease outbreaks.

2.2 As the world has acutely witnessed with COVID-19, global health threats significantly risk global prospects for security and prosperity. AMR represents a direct threat to UK and global health with bacteria, parasites, viruses, and other disease-causing microorganisms to become increasingly resistant to the drugs that are currently available. If left unchecked, this trend will result in pathogens that cause some of the most common diseases and medical conditions becoming untreatable.

2.3 The Fleming Fund focuses on increasing clinical and veterinary microbiology expertise, laboratory capacity, and developing active surveillance as core requirements for the effective diagnosis and surveillance of AMR. While AMR is a substantial health threat in its own right (as exemplified by its inclusion in the UK National Register of Civil Emergencies in 2015 and continued existence in the UK National Risk Register[1]), the programme also contributes an essential component of a strong health system. Over the past 18 months, the Fleming Fund has supported the COVID-19 response through its work on strengthening laboratory and workforce capacity. Whilst the Fleming Fund remains an AMR-focused programme, it is clear that the programme has cross-cutting benefits, and the Fund will continue to flex accordingly in Phase II.

2.4 As a result of COVID-19, the global surveillance context has shifted, and the operating environment for the Fleming Fund has changed since phase I, but this has only amplified the need for action on AMR. Surveillance is the lynchpin of an effective AMR policy response[2], and it is critical that the system supported by Fleming Fund aligns with wider global surveillance systems. The Fleming Fund

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[1] UK Government, CCS's National Risk Register 2020 (2020)
[2] Wellcome, The Global Response to AMR, p.21 (2020)

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will shift to align with the new and emerging global initiatives on surveillance, forming a key part of the UK's ambitions to 'improve global surveillance'[3].

2.5 Antimicrobial Resistance

2.5.1 Antibiotic medicines have been one of the most important breakthroughs in global healthcare and mankind's ability to reduce morbidity and mortality in the last century. In the light of this, growing resistance to antibiotic medicines poses one of the greatest threats to investments made in modern medicine and any further improvement in global health.

2.5.2 Preliminary results from a new Fleming Fund funded study, shared at the G7, found that AMR killed over 4.9 million people globally in 2019, more than HIV, tuberculosis, and malaria, strengthening the case for global action.[4] Often called the "silent pandemic", in 2017 it was estimated that unchecked AMR will cost:

- $100 trillion in cumulative global cost by 2050[5]
- 3.8% of global annual GDP by 2050, with an annual shortfall of $3.4 trillion by 2030[6]
- 24 million people forced into extreme poverty by 2030, threatening achievement of the Sustainable Development Goals (SDGs)[7]

2.5.3 However, the GRAM 2019 study indicates that the current AMR problem is greater than previously thought at the outset of this programme. It also confirmed that the problem is most felt in Africa and Asia, where the Fleming Fund interventions are targeted (see sections 12-14 of the Economic Case for more detail). This strongly reinforces the case for global action on AMR to reduce the current and future burden, and for action in Africa and Asia "hotspots".

2.5.4 AMR develops when bacteria adapt and grow in the presence of antibiotics. The development of resistance is linked to how often antibiotics are used. Because many antibiotics belong to the same class of medicines, resistance to one specific antibiotic agent can lead to resistance to a whole related class. Drug-resistant bacteria can circulate in populations of human beings and animals through food, water, and the environment. Transmission is also influenced by trade, travel and both human and animal migration.

2.5.5 AMR is a global challenge that will affect all countries, if not tackled, but increased resistance is likely to disproportionally burden LMICs. It is predicted that 90% of AMR related deaths will occur in Africa and Asia and that if unchecked, up to 24 million extra people could be forced into extreme poverty by 2030[8]. Factors which can worsen the scale of impact are:

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[3] UK Government, The Integrated Review 2021 (2021)
[4] Global Research on AMR (GRAM) project, Global burden of bacterial antimicrobial resistance in 2019, Institute for Health Metrics and Evaluation/University of Oxford (2021)
[5] P.15, Tackling Drug Resistant Infections Globally, The Review of Antimicrobial Resistance (2016)
[6] World Bank, Drug Resistant Infections, A Threat to Our Economic Future, P.19 (2017)
[7] World Bank, Drug Resistant Infections, A Threat to Our Economic Future, P.20 (2017)
[8] World Bank, Drug Resistant Infections, A Threat to Our Economic Future, P.20 (2017)

- The high prevalence of infectious diseases or conditions including for example tuberculosis, pneumonia, neonatal sepsis, and HIV in LMICs;
- Poor access to healthcare services including to diagnostic laboratories;
- Poor access to safe, effective, quality assured medicines including antibiotics and other antimicrobial medicines; and,
- Lack of effective regulation and supervision of the use of antimicrobial medicines in human health, animal health and agriculture.

2.5.6 The WHO report on surveillance of antimicrobial resistance[9] reported high global prevalence and increased frequency of AMR to many of the most important antibiotics in all parts of the world. The direct consequences of infection with resistant microorganisms can be severe, including, but not restricted to, longer illnesses, increased mortality, prolonged stays in hospital, loss of protection for patients undergoing operations and other medical procedures, and increased costs. However, the loss of effective antibiotics also compromises many other areas of health and medicine, with increased risk of prolonged illness or death from a failure to treat or prevent sometimes very basic infections.

2.5.7 The 4th June 2021 G7 health ministers' meeting communiqué emphasised the "*need for more immediate action to strengthen capacities for preventative measures at the human-animal interface, as well as surveillance of potential disease outbreaks, and in particular zoonotic diseases in humans and animals (including from wildlife, domestic and livestock and aquatic animal species) and antimicrobial resistance. (…) This means making the One Health approach, which also incorporates climate change, conservation, and sustainable use of biodiversity, central to our thinking on health security and future resilience including by supporting global and local cross-sectoral actors in geographic settings vulnerable to the emergence and spread of pandemic threats. We need to make better use of advances in our ability to collect, analyse, use, and share human, animal, plant and environment health data and enable faster collaboration in order to anticipate, assess the risk of and respond to health security threats. This interconnectedness needs to capture formal and informal information, data and sample sharing, including accessing multisectoral surveillance from human, animal, plant, food, climatic and aquatic health chains.*"[10]

2.6 AMR Impact on Human, Animal and Environmental Health

2.6.1 Improvements in global health over recent decades are under threat because the microorganisms that cause many common human diseases and medical conditions – including HIV/AIDS, sexually transmitted diseases, urinary tract infections, blood-stream infections, and food poisoning – are becoming resistant to a wide range of antimicrobial medicines.

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[9] World Health Organization, Antimicrobial Resistance: Global Report on Surveillance (2014)
[10] G7 Health Ministers, G7 Health Ministers' Meeting, communique (2021)

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2.6.2 Some of the most common childhood diseases in developing countries – malaria, pneumonia, other respiratory infections, and dysentery – can no longer be cured with many older antibiotics or medicines. In LMICs, effective and accessible antibiotics are crucial for saving the lives of children who have those diseases, as well as other conditions such as bacterial blood infections. Neonatal sepsis is a major concern in low resource settings. In all countries, some routine surgical operations and cancer chemotherapy will become less safe without effective antibiotics to protect against infections. Doctors must increasingly use "last-resort" medicines that are more costly, may have more side effects and are often unavailable or unaffordable in LMICs. Some cases of tuberculosis and gonorrhea are now resistant even to antibiotics of last resort.

2.6.3 For farmers, animal husbandry and the food industry, the loss of effective antimicrobial agents to treat sick animals damages food production and family livelihoods. An additional risk for livestock workers is exposure to animals carrying resistant bacteria. For example, farmers working with cattle, pigs and poultry that are infected with livestock associated methicillin-resistant *Staphylococcus aureus* have a much higher risk of also being colonised or infected with these bacteria. Food is one of the possible vehicles for transmission of resistant bacteria from animals to human beings and human consumption of food carrying antibiotic-resistant bacteria has led to acquisition of antibiotic-resistant infections.

2.6.4 Other risks for infection with resistant organisms include exposure to crops treated with antimicrobial agents or contaminated by manure or slurry, and farmyard run-offs into groundwater. Antimicrobial agents are commonly used in plant agriculture and commercial fish and seafood farming. The potential impact of antimicrobials in the environment, which may arise from use in agriculture and human or industrial waste, is also of concern to many.

2.6.5 Resistance to all antimicrobials, including antivirals and anti-fungals, is increasing, but of greatest concern is the rapid development of bacterial resistance to antibiotics. If the number of hard-to-treat infections continues to grow, then it will become increasingly difficult to control infection in a range of routine medical care settings. Furthermore, it will be more difficult to maintain animal health and protect animal welfare without taking further protective action.

3. Global Health Security

3.1 Global Health Security is a Prime Ministerial priority in the Integrated Review[11], especially in the context of COVID-19 response and preparedness to tackle future health threats. As AMR spreads, infections that would ordinarily be treatable are becoming a much greater threat and risking the UK's global health

[11] HM Government, Global Britain in a Competitive Age: the Integrated Review of Security, Defence, Development and Foreign Policy (2021)

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security. The UK government's National Risk Register[12] pays particular importance to AMR, warning that "*we are heading rapidly towards a world in which existing antimicrobial treatments no longer work*".

3.2 Internationally, the World Health Organization (WHO) declared AMR one of the top 10 global public health threats and passed a resolution to address the issue, resulting in the formation of the Tripartite's (WHO, FAO, OIE) Multi-Partner Trust Fund (MPTF). The former Director of the WHO Dr Margaret Chan has stated that: "*AMR poses a fundamental threat to human health, development and security.*"

3.3 By strategically supporting development of the evidence base driving national priorities and programmes, the UK through the Fleming Fund has created demand and pressure for further investment on AMR within countries and by international donors. Examples of wide and ongoing UK leadership include:

- 2014: commissioning Lord O'Neill's independent AMR review
- 2015: shaping the global action plan for AMR and becoming co-chair of the Ministerial alliance of Champions against AMR
- 2016: playing the leading role in the UN political declaration on AMR at the UN General Assembly
- 2019: Dame Sally Davies becoming co-convenor of the Inter-Agency Coordination Group (IACG) for AMR
- 2021: helping to establish the Global Leaders Group on AMR
- 2021: enshrining AMR as one of four key strategic actions for the G7 Health Ministers as the summit host

3.4 At home, the Fleming Fund also contributes at a global level to other UK Government department priorities, particularly following the COVID-19 pandemic (see Annex A for full list). Overall, the House of Commons Health and Social Care Committee report of October 2018[13] concluded "Given the severity of the threat, AMR needs to be firmly established as a 'top five policy priority' for the Government as a whole, drawing together the work of DHSC, Defra, DFID, the Foreign Office and BEIS."

3.5 The programme aligns with the 2021 UK Integrated Review of Security, Defence, Development and Foreign Policy, which emphasises the need to strengthen the UK's preparedness for future pandemics by harnessing the potential of data to improve global surveillance through taking a One Health Approach.

3.6 The Fleming fund is also closely monitoring new regional and global surveillance initiatives to ensure alignment and management of risks and opportunities (see Annex B for full list).

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[12] HM Government, CCS's National Risk Register 2020 (2020)
[13] House of Commons Health and Social Care Committee, Antimicrobial Resistance (2018)

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4. The Fleming Fund

4.1 The Fleming Fund is the first and single largest Official Development Assistance (ODA) investment in AMR surveillance. Established in 2015 to align with specific recommendations set out in the global action plan on AMR, the UN Interagency Coordination Group (IACG) framework for action, and the AMR review led by Lord O'Neill, phase I of the Fleming Fund was launched with a total allocation of £265 million from the UK's ODA budget. The Fund tackles AMR in LMICs through a portfolio of regional, country, and specialised grants, fellowships, and global projects (see Annex C).

4.2 Phase I grants were categorised into four workstreams (figure 1.1), with most of the funding allocated to the management agent to strengthen national surveillance systems. To accommodate the expansion and shift of work over the 3 -year investment period to respond to the shift in AMR and global surveillance context, phase II groups grants into five types of investment needs (figure 1.2, next page).

Figure 1.1: Phase I investment pyramid

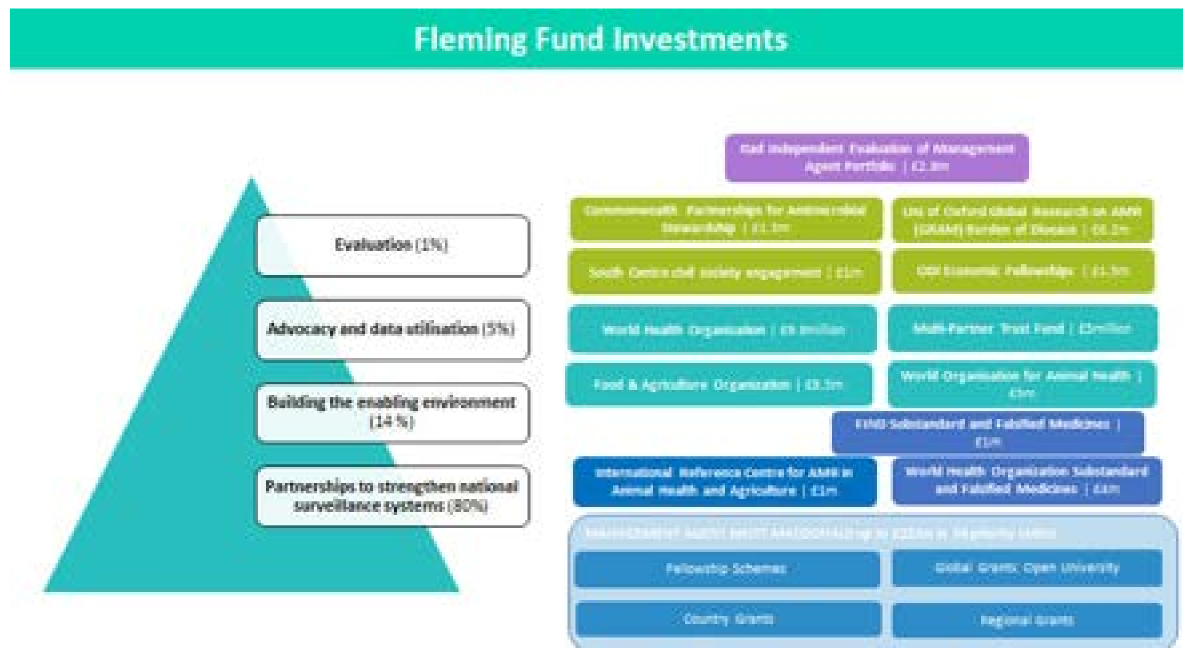

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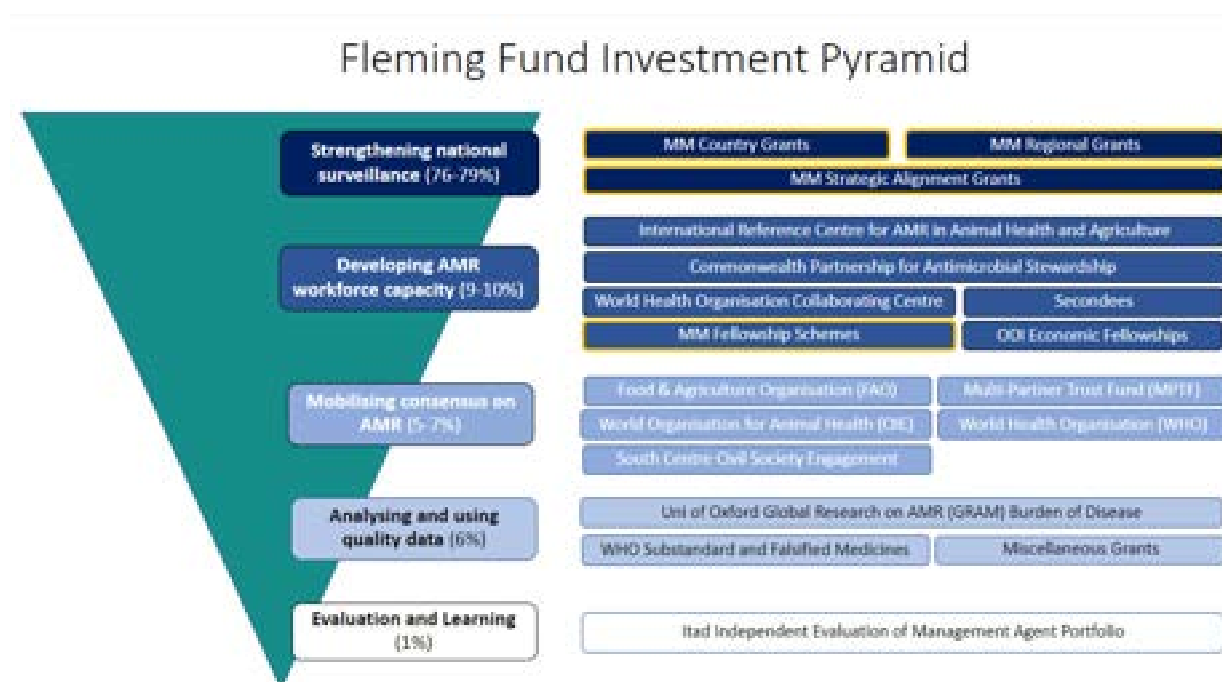
Figure 1.2: Phase II investment pyramid



4.3 The content of the Fleming Fund programme is covered in more detail in Annex C, but in summary comprises:

i. **Strengthening national surveillance**, including building surveillance systems, ongoing regional services and building scientific capacity in countries;

ii. **Developing AMR workforce capacity**, including supporting AMR capability globally, nationally, and regionally as well as embedding stewardship into the Fund's activities;

iii. **Mobilising consensus on AMR** and on actions to take, increasing national and regional support and catalysing change in clinical activity;

iv. **Analysing and using quality data**, which will help integrate AMR into the global burden of disease and improve awareness on AMR; and

v. **Monitoring, evaluating, and learning (MEL)**, so as to assess the fund's success through regular evaluations and plan course corrections to improve efficiency.

4.4 It is important to note that these elements overlap and complement each other. For example, strengthening national surveillance programmes includes work on analysing and using quality data at a country-level, complementing the Fleming Fund's targeted work at the global level.

4.5 The Fleming Fund currently operates in 21 countries across Sub-Saharan Africa, South and South-East Asia, selected in phase I based on the following criteria:

- ODA eligible, so that the country can receive the funds;

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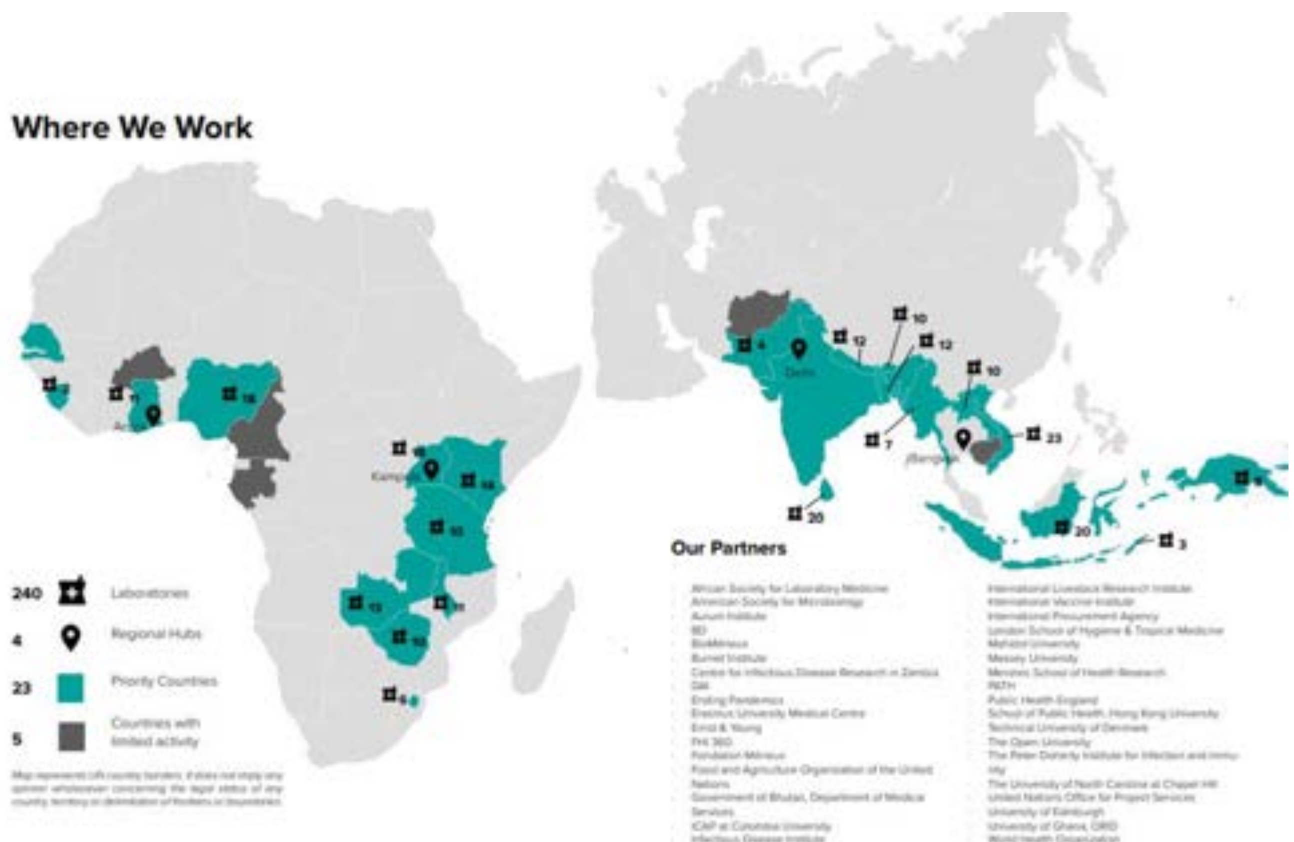
- Located in Sub-Saharan Africa, Southern or South Eastern Asia – regions that reported the least or no data on AMR;
- Fragile states will be considered, however conflict countries[14] will not be considered.

4.6 32 countries found eligible for funding, were narrowed down to 24 by the Management Agent, who performed desk-based reviews and key informant interviews to determine capability, risks, context, and threat to the UK from transmission of infection in each region and country. Three countries are no longer eligible due to increased political instability.

4.7 The Fleming Fund supports countries to develop One Health AMR National Action Plans (NAPs) and contributes to strengthening health systems in LMICs through diagnosis, surveillance and use of quality health data related to AMR.

4.8 The programme currently operates in Bangladesh, Bhutan, Eswatini, Ghana, **Indonesia***, **India**, **Kenya**, Laos, Malawi, Nepal, **Nigeria**, **Pakistan**, Papua New Guinea, Senegal, Sierra Leone, Tanzania, Timor-Leste, Uganda, **Vietnam**, Zambia, and Zimbabwe (*priority countries in bold).

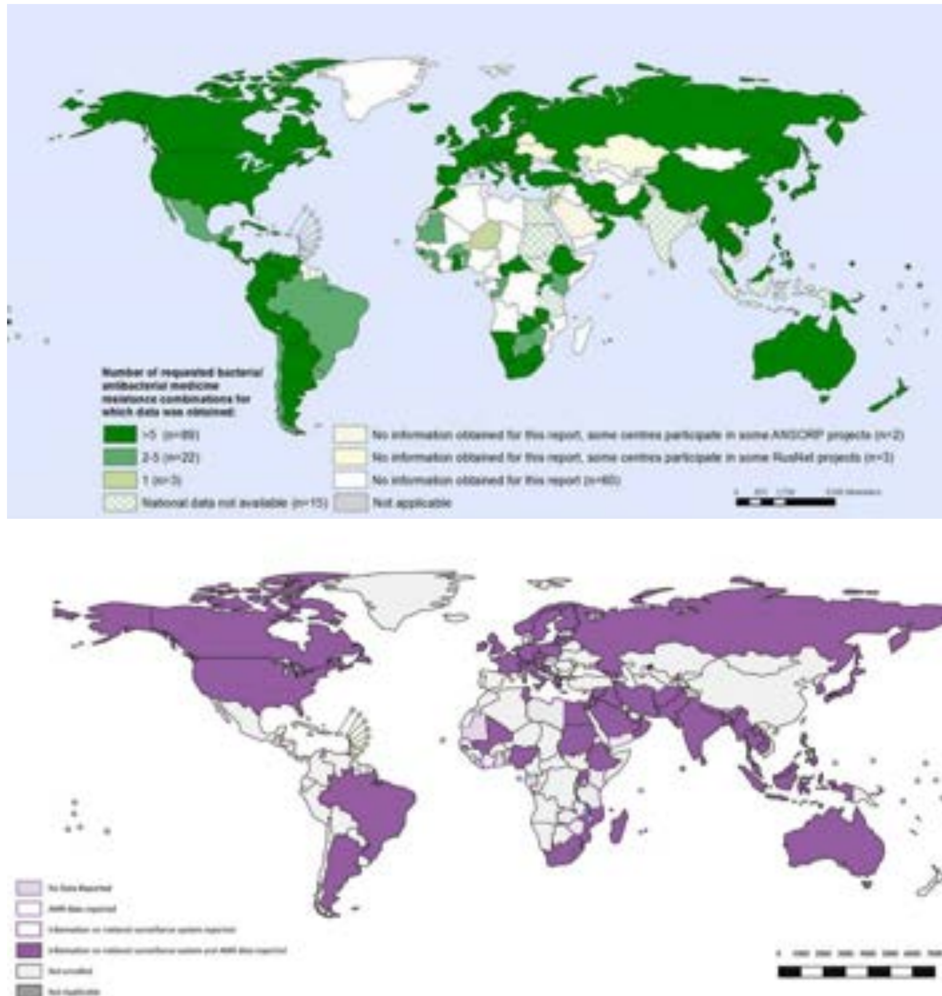
Figure 1.3: Regional Map of Fleming Fund Countries



[14] For the purposes of the fund please consider conflict countries to be countries where an active conflict is nationwide; however, the fund may work in countries with pockets of conflict or fragility but where there is potential to develop a sustainable surveillance system.

4.9 Phase I of the Fleming Fund has already made a positive impact on a global scale. Comparing the WHO 2014 global report[15] with the 2020 Global Antimicrobial Resistance and Use Surveillance System (GLASS) report[16] shows that 12 more Fleming Fund countries in South Asia and Africa have begun to implement national surveillance systems and report AMR data (see figure 1.5). This data has been put to good use by the Global Research on Antimicrobial Resistance (GRAM) project to increase knowledge on AMR burden data.

Figure 1.4: Country level provision of AMR data, 2014 (above) and 2020 (below)



4.10 The Fleming Fund has also contributed to increased global awareness of AMR, with an average of 1,500 new visitors to the website every month and an annual Delivery Partners Event that allows partners to share good practices and collaborate instead of working in silos. Our Management Agent delivers webinars, and FF grantees hold conferences and symposiums to continue to

[15] WHO, Global status report on noncommunicable diseases (2014)
[16] WHO, GLASS early implementation report, (2020)

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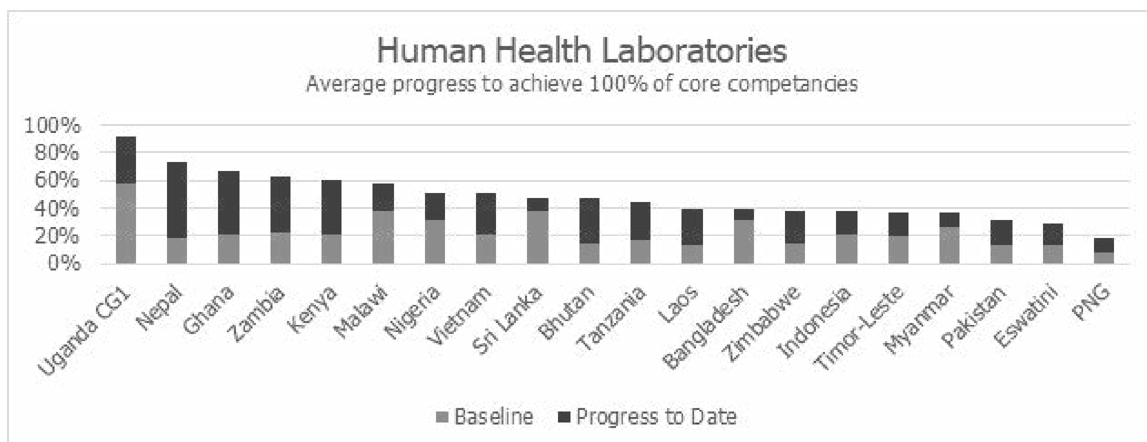
share data and achievements. The Fund has helped implement National AMR reference centres, streamlining and homogenising the collection of national data in several countries. In addition, the Fund has helped train over 15,000 healthcare staff and supported 240 laboratories to improve capacity for the diagnosis of infections in LMICs.[17] Many of our grantees – such as the OIE, WHO and GRAM – have disseminated reports on AMR data in human and animal health, substandard and falsified medicines, and the burden of AMR. Specific case studies of phase I successes can be found in Annex D.

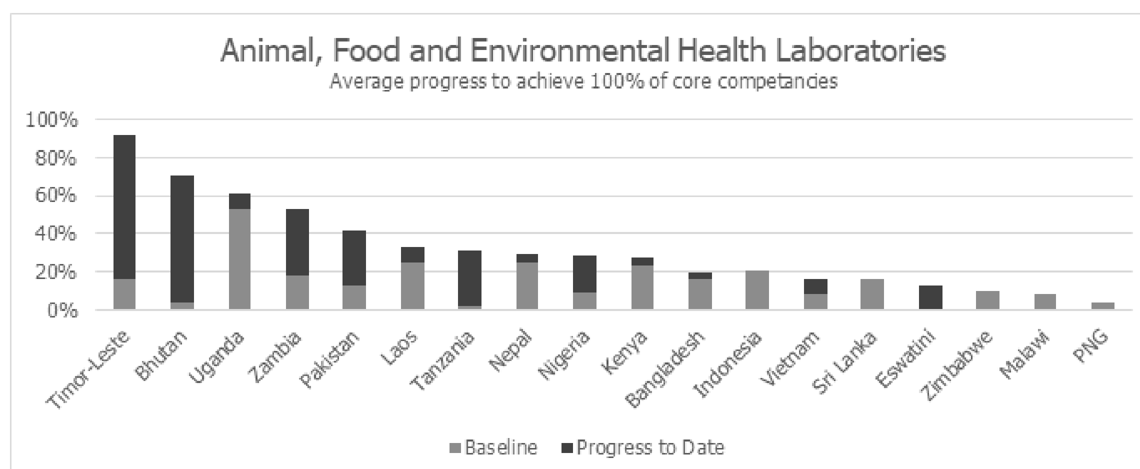
4.11 The Fleming Fund has made significant contributions to Human Health laboratories in all charted countries in figures 1.5 and 1.6, particularly Nepal and Ghana in phase I, as demonstrated by the progress against the LSHTM roadmap. The charts below show aggregated laboratory site progress up to and including Q4 2020 for each country as per requirements and standards for core level in appendix E of the LSHTM roadmap. Although the core competencies are not expected to reach 100% by the end of 2022 due to delays, significant progress has been made and core competencies are expected to reach 100% by the end of phase II.

Figure 1.5 Human Health Laboratories: progress to date



[17] DHSC, Fleming Fund Annual Review: January to December 2020 (2021)

Figure 1.6 Animal, Food and Environmental Health Laboratories: progress to date



4.12 The Fleming Fund also contributes to wider UK and Global initiatives on global health systems strengthening and pandemic preparedness and will continue to pursue these secondary benefits in phase II. In phase I, the Fleming Fund has flexed to support the COVID-19 response effectively through investing in equipment and capabilities which have value in detecting AMR and other diseases, most recently and notably seen in the Fleming Fund's investment in a whole genome sequencing regional grant which helped support detection of the Omicron variant in South Africa.

4.13 The work of the Fleming Fund has also supported the UK government's diplomatic aims on global health. For example, the UK Ambassador to Indonesia called the Fleming Fund partnership the 'backbone for the development of the UK-Indonesia bilateral MoU on Health Cooperation'.

4.14 Despite strong evidence of progress, there is a need for ongoing investment in AMR. As the global COVID-19 pandemic has illustrated, major outbreaks of disease that do not have treatment and other public health emergencies are amongst the most significant threats to society, endangering lives, and disrupting public services and the economy. COVID-19 has taught the world the importance of effective surveillance in identifying global health risks early and tracking their development. This is as true for a pandemic infection such as influenza or a coronavirus, as it is for the emergence of deadly drug resistant infections, such as those covered by the Fleming Fund.

5. The Case for Change

5.1 In 2017, global AMR-related deaths were predicted to rise to 10 million by 2050, with 90% of all AMR deaths occurring in Africa and Asia. At a cumulative cost to global economic output of $100 trillion, LMICs will be disproportionately affected, given the higher prevalence of infectious disease, and predicted greater drops in economic growth, which overall risks undermining the achievement of the 2030 SDGs.

5.2 However, new data indicates that AMR is much more significant global and regional burden than previously thought. The initial global estimates from the Global Research on AMR (GRAM) Project indicate that:

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- In 2019, there were 1.27 million (95% UI 0.911–1.71) deaths attributable to AMR (based on the counterfactual of infection with a susceptible organism). This would make bacterial AMR the 12th-leading underlying cause of death, ahead of HIV, tuberculosis, and malaria.

- In 2019, 192 million (146–248) Disability Adjusted Life Years (DALYs) were associated with AMR and 47.9 million (35.3–637) DALYs were directly attributable to drug resistance.

- In 2019, there were 4.95 million (3.62–6.57) deaths associated with AMR (based on a counterfactual of no infection). This would make bacterial AMR the 3rd-leading underlying cause of death, behind only ischaemic heart disease and stroke.

- Death rates were highest in the sub-Saharan African regions and lowest in Australasia.

5.3 The COVID-19 pandemic has prompted the overuse of antibiotics globally, further increasing risk of AMR.[18] The WHO estimates that while 15% of severely ill COVID-19 patients need antibiotics to treat secondary infections, in practice, over 75% of patients were administered antibiotics worldwide.[19] The link between this and AMR is not yet established, but experts predict it will not only drive the development of resistance, but will also cause antibiotic shortages and increase the likelihood of substandard or falsified medicines being administered.

5.4 Prospects for domestic or other-donor financing are poor in the short-term in most Fleming Fund priority countries. The Fleming Fund has observed overall low appetite for ODA investments by other countries for AMR, due to a lack of data on the economic case for investment – which the Fleming Fund continues to address in phase II – and the lack of a single catch-all solution. This means that UK investments, through the Fleming Fund and other related UK ODA programmes on AMR and GHS, remain an essential contribution to tackling global health challenges. Supporting LMICs to generate data highlights the scale and severity of the issue and allows countries to calculate the cost and benefit of investment in surveillance, which should increase domestic investment and/or leverage other donor funding in the longer term. As the case for action grows stronger, other actors such as the European Investment Bank are beginning to contribute towards AMR project funding.

5.5 AMR has rarely been seen as a top priority issue by policy makers, clinicians or by the aid organisations working in LMICs. Although the Fleming Fund has improved the amount of data available on AMR, surveillance takes time and requires resources to become embedded. AMR may get lost amidst the other, more immediately obvious priorities to decision makers who may not receive AMR data on a regular basis. Treatment failure is common, but often not ascribed

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[18] National library of medicine, national centre for biotechnology information, Antibiotic prescribing in patients with COVID-19: rapid review and meta-analysis (2021)
[19] WHO Europe, Stop the COVD-19 pandemic from becoming an AMR catastrophe (2020)

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to AMR, and disentangling the cause between poor diagnosis, poor care, substandard drugs, comorbidities, and AMR (or a combination of all), is almost impossible.

5.6 To ensure AMR is prioritised, key international, national, and local stakeholders need to have evidence of both the trends of resistance and the impact that this is having on the health of their populations or, importantly, the efficacy of the medicines they are buying.

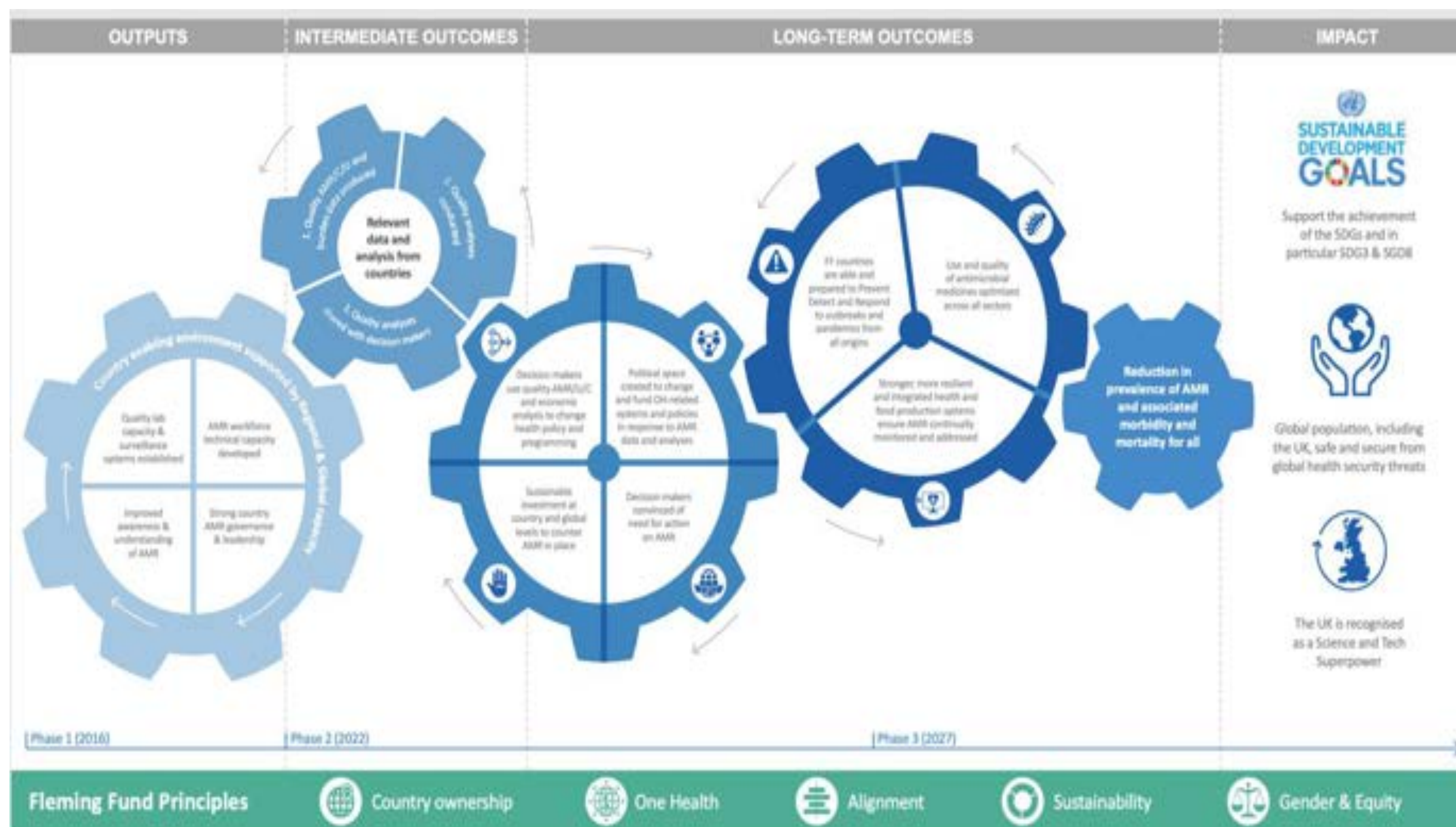
5.7 DHSC has the opportunity to build on investments to date through the Fleming Fund's core principle of country ownership. In supporting LMICs to develop their own National Action Plans (NAPs), changing practice and attitude towards AMR and AMC, and training healthcare staff who can then pass on their knowledge to others, the Fleming Fund ensures that the UK government's support to LMICs to generate, share and use AMR data is embedded and sustainable (see Strategic Case, section 12.3).

5.8 To realise the long-term impact of the Fleming Fund, a longer timeframe for delivery is needed. The Fleming Fund's revised Theory of Change (figure 1.8 on the following page) shows how intermediate outcomes such as those seen in phase I can translate into embedded good practices and noticeable change over the next three years during phase II. Adopting a 10-year strategy with the inclusion of a possible phase III after 2026 will embed addressing AMR globally through strengthened LMIC health systems.

5.9 As seen with the COVID-19 pandemic, infectious diseases and antimicrobial resistance are not restricted by national borders. In our global society, in supporting LMICs in their surveillance and good practice of AMR, the UK reduces the risk of new resistances forming and eventually appearing within UK territory. Therefore, the Fleming Fund's activities will reduce AMR as a health security threat to the UK population, while the provision of training and development of new technology contribute to the UK's role as a world leader in science and technology.

5.10 Taking a long-term view as described in the Theory of Change will allow time for other donors to invest in AMR and for partner governments to direct national resource towards AMR, as the scale of the challenge and possible solutions become clearer. It reflects the time taken to deliver results for other innovative disease prevention programmes and aligns with delivery of the SDGs.

Figure 1.7: Fleming Fund Theory of Change[20]



[20] Revised for phase II in consultation with the Programme Monitoring, Evaluation and Learning Advisor, external evaluator, delivery partners and other partners in the context of the DHSC GHS Theory of Change

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5.11 Successful disease control programmes require careful management and continued investment to embed sustainably. For example, the WHO declared TB a “global emergency” in 1993, leading to a decrease in TB-related mortality by 47% over the next 30 years. However, TB remained the leading cause of death from a single infectious agent in 2016, with 1.7 million deaths worldwide. To compare, AMR caused 1.27 million deaths worldwide in 2019, and it will take time to increase surveillance capacity and change national health planning policy.

5.12 It is important to note that slower than expected roll-out impacted phase I programme delivery. The pre-grant phase of country engagement with national governments proved to be a critical, high value period in supporting country leadership and action on AMR, taking on average 12 months from engagement to beginning grant activity, whereas the Fleming Fund team had anticipated the agreement of two 18–24-month contracts per country within the 5-year phase I period. However, later country grants to be agreed only started activity in early 2021, the last being India, which was agreed in the summer, with limited implementation time ahead of the end of phase I.

5.13 Reasons for this include the longer inception period for the Management Agent than planned, and COVID-19, which has increased delays in activities, exacerbated by low revenue and weak health systems in LMICs. The Fleming Fund experienced several challenges in addition to the COVID-19 pandemic when setting up the programme from scratch, which involved (but was not excluded to) establishing 4 regional hubs, recruiting expert staff, the lack suitable candidates for running grants. In addition, there was a high administrative burden, such as when UN agencies were involved in negotiations, or multiple departments were involved in signing Memorandums of Understanding (MoU) in order to receive national government approval.

5.14 The Fleming Fund’s adaptive management approach has ensured the programme has continually learnt and improved through-out phase I. Learning to date has been captured formally in the first formative evaluation report, the annual reviews commissioned by DHSC, and in the quarterly and annual reports from grantees including from the Management Agent. The work of the Fleming Fund has also been assessed by the Independent Commission for Aid Impact (ICAI) in its January 2018 review “The UK aid response to global health threats”.[21]

5.15 The Fleming Fund phase II is expected to start in a significantly better position, drawing on existing country infrastructure and mechanisms, as well as an experienced Management Agent whose performance has improved over phase I (see section 1 of the Commercial Case).

6. Strategic and Investment Objectives

6.1 The aim of the Fleming fund is to support LMICs to generate, share and use data to improve antimicrobial use and encourage investment in AMR. A set of targeted

[21] ICAI, The UK aid response to global health threats, (2018)

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objectives to achieve this aim will ensure that LMICs, currently unable to collect data on trends in antimicrobial resistance and antimicrobial use are better able to do so through ongoing surveillance of AMR in human and animal populations, which can support efforts to tackle and control the spread of resistant infections. These are:

- **Objective 1**: strengthen national AMR surveillance, laboratory, and workforce capacity in up to 25 priority countries.
- **Objective 2**: improve global understanding of the threat of AMR by providing quality antimicrobial resistance, consumption, and use (AMR/C/U) evidence for global advocacy and policy.
- **Objective 3**: increase awareness and the use of AMR and AMU data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.

6.2 The targeted objectives of the programme are strongly aligned with SMART principles as set out below.

- Specific – Three specific objectives delineate the purpose of targeted investment (paragraph 6.1).
- Measurable – The Fleming Fund will assess its activities against the revised Theory of Change's outputs and outcomes (figure 1.7).
- Achievable – Each of the countries has undergone a desk-based assessment to ensure that they are legitimate targets of the fund. The Fleming Fund reassesses all grants on a regular basis to check the achievable scale of activities.
- Realistic – The Fund is rightly ambitious and is subject to routine external scrutiny as well as periodic reviews to ensure that assumptions are fully tested and that the funds objectives can be realistically achieved given the level of resource available to overcome barriers.
- Timely - The Fleming Fund works with grantees to develop annual workplans with quarterly milestones that relate to results-based payments linking to the Theory of Change.

6.3 The Fleming Fund will continue to focus on supporting LMICs to generate, share and use robust and quality assured AMR, AMC, and AMU data. Phase II will aim to broaden the depth and breadth of activity, and strengthen the usability, relevance and quality of data collected by emphasising five main areas:

- **Greater use of AMR data:** The heart of the Fleming Fund will continue to be a focus on data: supporting LMICs to generate, share and use robust and quality assured AMR data. This will include supporting further costing and implementation of National Action Plans and working with governments to build a policy environment to act on data generated.
- **Making the economic case:** This concept is addressed in depth in the economic case as it is essential to ensure AMR is prioritised at country, regional and global levels. The Fleming Fund will continue to invest in the assessment of burden in disease in humans, as well as collecting data on consumption and use of antimicrobials in agriculture and animal health.

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- **Greater focus on One Health**: One Health recognises that the health of humans is connected to the health of animals and the environment. The Fleming Fund specifically focuses on the necessity to tackle AMU and AMR in animals, agriculture, and the environment due to the ease of transmission of infection. In phase II, all projects should demonstrate understanding of the One Health concept, and how evidence-based policies require continuous collaboration from public health, veterinary medicine, and agricultural practices.
- **Greater focus on regional animal health:** The Fleming Fund will work closely with colleagues in Defra – VMD, APHA, Cefas – on targeted animal and aquaculture projects at a regional and global level in addition to the One Health approach. This will help inform global understanding of governance and use of antimicrobials in animals.
- **Progressing data collection on substandard and falsified (SF) medicines**: The Fleming Fund will also further work to establish the importance of collecting data on SF medicines, supporting countries' capacity to address antimicrobial use through their medicines' regulatory capacity. This will include working closely with the tripartite to identify synergies between data on AMR and SF medicines.

6.4 New Country Partnerships in phase II: The Fund will explore extending country partnerships to an additional 2-3 countries between 2022 and 2025. The new countries will be selected using a series of primary and secondary criteria, and consultation processes that will help to manage environmental and political risk, ensure feasibility, optimise impact, value for money and coherence with broader HMG global / regional priorities. The selection process is set out in Annex E.

6.5 As seen in the Theory of Change (figure 1.7), the fund will continue to operate to its four core principles from phase I, with the added principle of Gender and Equity:

- **Country Ownership:** Country grants are designed in partnership with country governments and their agencies, so that the support provided accords with national needs and priorities. This takes time to achieve but will be more sustainable and cost effective in the longer term.
- **Alignment:** The Fleming Fund recognises the importance of coordination and alignment with UK policy and national and international programmes, with other international (aid) donors and with other programmes and investments within each country and region. This approach is key to supporting the UK position globally, and to ensure cost effective and sustainable investment at a country level.
- **Sustainability:** The Fleming Fund Grants will focus assistance on national systems with a view to long-term sustainability. Investment size and scope will, as far as possible, be aligned with national government spending so that systems created with Fleming Fund grants are sustainable within the national public health system.
- **One-Health:** The Fleming Fund recognises the critical importance of animal health, agriculture, and the environment in addressing AMR and invest where needed across all sectors.

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- **Gender & Equity:** The Fleming Fund recognises that AMR impacts people of different characteristics in a variety of ways[22]. Phase II will include further work on value for money (VfM) to build in equity and ensure gender sensitivity is embedded in the Fund's investments.

6.6 To support the above strategic objectives and core principles, the Fleming Fund will strengthen its existing partnerships and build new ones with other organisations as seen in figure 1.8 below.

Figure 1.8 Fleming Fund partner organisations

Partner type	Role
UK Government Departments and Agencies (FCDO, Defra, PHE/UKHSA, VMD, MHRA, NIHR)	•Ensures use of world leading UK expertise •Aligns Fleming Fund with other international programmes (e.g. Quality of Medicines)
Global Foundations (Wellcome, Fondation Merieux, Institut Pasteur)	•Overseas research programmes in clinical research •Opportunity to support microbiology laboratory capacity development in up to 29 low income countries •Opportunity to align and cooperate with countries and regions
Regional Institutions and Centres of Excellence (Africa CDC, ILRI Kenya, International Vaccines Institute, Korea, ICARS, asIRLI, World Fish Malaysia)	•Continuation of Phase I engagement through country and regional grants •Opportunity to collaborate or partner with new institutions in phase II
Professional Bodies and International Federations (e.g. Sri Lanka College of Microbiologists, International Association of National Public Health Institutes, International Federation of Pharmaceutical Manufacturers Association, AMR Industry Alliance)	•Provide effective means of professional engagement, communication and information dissemination to relevant workforces •Play a leading role in setting standards and developing operational guidance
Regional Economic and Development Groups (ASEAN, SADEC, ECOWAS)	•Contribute to leadership, cooperation and harmonisation between economic development and health •Example: relationsip between the use of antimicrobial medicines in terrestrial and aquatic livestock, their economic importance, and the importation of medicines in LMIC countries.
Not-for-profit Organisations (PATH, FIND)	•Support health and agricultural services through activities such as research.
Research Organisations and Networks (UKRI, JPIAMR, SEDRIC)	•Although not supported by the Fleming Fund, the Funds strong relationship with the research community is vital to effective surveillance.

[22] More information on the necessity to focus on gender in the fight against AMR can be found in WHO, Regional Office for Europe's 2019 report.

6.7 Results from phase I show good progress in the Fleming Fund's breadth of influence and ability to leverage other Global Partner's investments in AMR surveillance. Areas of Fleming Fund influence include:

- The development of programmes led by Wellcome, CDC Atlanta, Southeast Asia Health Security Donor Coordination Group and Australia's Department for Foreign Affairs and Trade.
- Core membership of a World Bank AMR donor group.
- Providing investments as a platform for the DHSC-led G7 proposal for a One Health Intelligence Hub, where AMR is expected to feature strongly.
- The coordination with the Bill and Melinda Gates funded ($100m) Africa Pathogen Genomics Initiative and successfully lobby for the programme to focus initial activity on AMR in Whole Genome Sequencing.
- Membership of the UN's Multi-Partner Trust Fund on AMR, increasing global influence, specifically with other donors and the Tripartite.

7. Scope of Investment

7.1 Phase I of the Fleming Fund was approved with a budget of £265 million through various approval processes for the management agent and evaluation supplier, as well as for the smaller grants. These can be found at Annex F. A number of phase I grants have been extended into 22/23 to allow for a better transition to phase II activities. Details of these extensions can be found in the Financial and Commercial Cases and at Annex G.

7.2 This case addresses all Fleming Fund grants and activities (see figure 1.2 for existing grants), building on the work of previous business cases to detail a strategy for delivering the Fleming Fund's strategic objectives.

7.3 The case recommends:

- Renegotiating the Management Agent contract to better deliver outputs and outcomes according to phase II priorities.
- Continuing the extension of the Evaluation Agent contract as negotiated in the 2017 Business Case.
- Negotiating new contracts and grants with the relevant current delivery partners to adapt activities according to phase II priorities. As the Fleming Fund develops plans for phase II, the team may also consider new grants/delivery partners for some smaller grants and will work with commercial/grants hub if this is the case.
- Extension of the Management Agent and Independent Evaluator contracts up to March 2026, to allow for planning and continuous delivery of key activities. Contracts will have clear break clauses included at end of year 3 to ensure DHSC can exit contracts should sufficient funding not be secured in the next

Spending Review. Investment Committee approval to spend the funds in year 4 will be sought in year 3.

8. Measuring Success

8.1. As an ODA funded programme, the primary beneficiaries are the populations of LMICs, who will ultimately benefit from improved infectious disease diagnosis and treatment, leading to improved health and economic well-being. National governments will benefit from the use of local data to inform policy decision making and investment priorities for addressing infectious diseases and AMR, and for optimising use of antimicrobial medicines. Clearer data and improved practices on the use of antimicrobial medicines in agriculture and aquaculture will help LMICs access export markets, providing them with a direct economic benefit. Finally, the UK will indirectly benefit through the increase in global awareness of AMR and better antimicrobial stewardship worldwide.

8.2. Whilst difficult to quantify the cost savings or lives saved at this initial stage of the Fleming Fund project and in global efforts to tackle AMR, the project will aim towards achieving the above results and measure this success against the outcomes and core values established in the Theory of Change (figure 1.7) as seen in the below table (figure 1.9) (See section 10 of the Management Case for more detail on Monitoring, Evaluating and Learning).

Figure 1.9: Fleming Fund Example Expected Outputs

Intermediate Outcome	Example contributions
Quality AMR/C/U and burden data produced	Key personnel are trained in epidemiology and surveillance methods for human, animal, and environmental health laboratories and/or national coordination centres for AMR. Proficiency Testing schemes are developed for antimicrobial susceptibility testing of priority pathogens and commensals. A comprehensive global database on the use of antimicrobial agents in animals over time is developed.
Quality analyses conducted and options to tackle considered	Advice and support are given for the adaptation and implementation of alternatives to antibiotics. Skilled health economists are placed in LMIC agencies. Estimation of burden of sepsis from all pathogens combined
Quality analyses presented and shared	Assessing and improving detection methods, including through field screening equipment and laboratory networks, for greater capacity to test SF medical products. Regional bodies are supported to identify policy bottlenecks around data sharing. Cross-partnership lessons learning and sharing of best practice and results are facilitated.

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8.3. Following advice from the Fleming Fund Technical Advisory Group to recognise that countries are starting from varied baselines with their AMR surveillance capacity, DHSC and the Management Agent have established the following (figure 1.10) country capability levels. This creates a standardised pathway of progress across countries, aimed at allowing the evaluation of success criteria (see Annex C for more information on country grant activities).

8.4. **The Fleming Fund's ability to withdraw funding**

8.4.1 The responsibility for stopping funding to a country will depend on the type of risk (Operational/Reputational/Financial). Halting funding to a specific country would, in the first instance, be at the discretion of the Global Health Security programme board (chaired by the programme SRO, SCS 2) and potentially in a recommendation to DHSC Ministers if sensitive.

8.4.2 For example, following political instability in Myanmar during phase I, the Fleming Fund consulted the FCDO on whether to continue aid to the country given the high operational risks. Following advice from the FCDO, the Fleming Fund requested permission from DHSC seniors to terminate the country grant, and then informed Ministers of the decision.

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9. Legal obligations

9.1 Public Sector Equality Duty

9.1.1 The Court of Appeal ruled that the Public Sector Equality Duty (PSED), established by section 149 of the Equality Act 2010, applies to Ministerial decisions even when the consequences of those decisions will be exclusively felt outside the territorial limits of the UK. This means that the PSED applies to all decisions taken in relation to the Global Health Security Programme.

9.1.2 The PSED requires you to have “due regard” to the need to:

a. Eliminate discrimination;
b. Advance equality of opportunity;
c. Foster good relations between people with a protected characteristic and those without.

9.1.3 The “relevant protected characteristics" are age, disability, gender re-assignment, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. The PSED also applies to the additional protected characteristic of marriage and civil partnership but only in relation to the requirement at (a) above. The PSED does not require any particular outcome, but it does require that decision-making take into account the above three considerations.

9.1.4 The Fleming Fund team have assessed that none of considerations above will be exacerbated or worsened by the operation of the Fund, and that they will be potentially improved through the Fund’s activities.

9.1.5 The programme actively manages the risk of discrimination in the delivery of activities. DHSC is committed to providing a workplace free from bullying, harassment, and discrimination, and one that promotes good working relationships, and has a robust reporting mechanism, grievance procedure and support system in place to deal with instances of this. In addition, non-discrimination and equal treatment are key principles of HMG procurement policy and are considered as part of contract and grant awards.

9.1.6 The Management Agent’s (MA) equality, diversity, and inclusion (EDI) policy establishes responsibilities and makes clear that unfair discriminatory behaviour will result in disciplinary action. The policy applies throughout their operations, irrespective of roles or location, including programme delivery. This includes compliance with equal opportunities legislation and promoting fair employment policies, within the framework of local culture and laws. The aim of the MA’s policy is to ensure that no job applicant or employee receives less favourable treatment, either directly or indirectly, on the grounds of age, disability, caring status e.g., parental/elder, gender, marital status, race, colour, nationality, ethnic origin, sexual orientation, or transgender. EDI and unconscious bias training are mandatory for all employees. The MA’s equality, diversity and inclusion team and advance employee network of champions are responsible for the promotion of awareness and appropriate behaviour and help to foster an inclusive workplace culture. In phase II, the Fleming Fund will continue to closely monitor contracts and grants awards to ensure they take an active role in eliminating discrimination from project activities.

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9.1.7 The aim of the project is to better understand and map where AMR is leading to morbidity and mortality. As with many public health issues, where results suggest a country has a specific hot spot of deaths attributable to AMR, it is likely that a high proportion of these are in poorer communities, those who are chronically sick or disabled, amongst pregnant women, mothers, and children. These groups are more likely to be regularly exposed to hazardous bacteria and communicable diseases. Additionally, their nutritional status or current health status may make it hard to fight these infections. The Fleming Fund anticipates providing data on the prevalence and trends of AMR to policy makers will help them to address specific AMR-related health issues in a more targeted way, therefore having an overall positive impact on these groups.

9.1.8 Being held back by poor health is a key determinant in poverty. As previously mentioned, AMR is a global challenge that will affect all countries, if not tackled, but increased resistance is likely to disproportionally burden LMICs. It is predicted that 90% of AMR related deaths will occur in Africa and Asia and that if unchecked, up to 24 million extra people could be forced into extreme poverty by 2030[23]. Indirectly the Fleming Fund project will tackle this issue through aiming to improve health and therefore reduce poverty.

9.1.9 Wherever possible, the Fund seeks to further economic opportunities for those from protected characteristic groups. The fellowship scheme, a programme which offers 6-18 months of tailored professional development and mentorship in AMR, has been tailored to ensure the Fleming Fund and its grantees have equal representation between different genders, or as equal as possible given the availability of AMR specialists in the specific country context. This approach will continue into phase II.

9.1.10 Wherever possible the project will seek to foster good relations between those with protected characteristics and those without. Operating in 21 or more countries, the Fund will engage people from a diversity of backgrounds and faiths. The Fleming Fund's regional grants and Fleming Fellowship programme will seek to promote the academic and operational integration of different groups, united in the goal of tackling AMR and creating functional communities of practice - groups of AMR practitioners who come together from across different fields and countries to collectively improve their approach to AMR surveillance and policy making.

9.1.11 In phase II of the programme, the Fleming Fund intends to use programme resources to improve global understanding of the intersection between AMR and those from marginalised groups, thereby having an overall positive impact on equality in the contexts in which grantees are operating. 'Gender and Equity' is a new principle introduced into the Fleming Fund Theory of Change for phase II and the Fleming Fund has developed an equity statement. Activities for phase II are currently being scoped but considerations will include: Ensuring lab analysis is presented to policy makers disaggregated by

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[23] World Bank, Drug Resistant Infections, A Threat to Our Economic Future, P.20 (2017)

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gender (the data is currently collected but not necessarily presented); options for community surveillance to directly assess impact of AMR on different community groups; and whether healthcare-seeking behaviours are impacting anti-microbial prescribing practices. The intersection between gender, equity and AMR is not well understood globally, and focusing on where the data can support further understanding of this will enable the Fleming Fund to catalyse change both in the specific contexts in which grantees are operating, and also more widely with the WHO and other development partners, ultimately leading to more focused policy making and clinical practice on AMR for disadvantaged groups globally.

9.2 Gender equality duty

9.2.1 The International Development Act 2002 (IDA) provides the legal basis for the Fleming Fund. The IDA permits the UK government to provide “any person or body” with development assistance if you are satisfied that this is likely to contribute to a reduction in poverty. The Secretary of State has a legal duty under s 1A of the IDA to have regard to the desirability of reducing gender inequality when giving development assistance under section 1(1). A number of epidemic diseases disproportionately affect women, so the Fleming Fund considers that these investments are likely to have a positive impact on gender equality in the longer term. Data generated from laboratory samples has been disaggregated by gender, which enables countries to develop policy and clinical interventions in a gender-sensitive way. The Fleming Fund Theory of Change, revised for phase II, has introduced ‘gender and equity’ as a fifth core principle which will also help to ensure all activities across the Fund take this into account.

9.3 Families Test

9.3.1 The Fleming Fund team have assessed the family test against the objectives and likely impacts set out in section 5 and 6 of the strategic case. None of the five questions are directly relevant. However, question 2 on the impact on families going through key transitions, and question 5 on the impact on families most at risk of deterioration both reference the burden on family members dealing with long term sickness. These questions have been considered, as improper use of antibiotics or use of antibiotics against resistant infections can prolong sickness. The long-term desired impact of the Fleming Fund is that AMR surveillance data will inform policy and more effective clinical decision making, ultimately reducing the burden of disease and impact on the family associated with AMR. This will become more relevant in phase II, as the Fund moves towards the delivery of outcomes.

10. Climate change considerations

10.1 The Fleming Fund has taken environmental protection into careful consideration for phase II activities.

10.2 **Greenhouse gasses**: The current Management Agent was independently certified as carbon neutral globally after obtaining PAS 2060 – the international standard for carbon neutrality – in 2020, ensuring all country and regional grant activities are carbon neutral. The Management Agent’s climate and environment

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advisory practice will be able to provide input into strategy for reducing the impact of the programme on greenhouse gases, although the Fleming Fund does not currently have a mechanism for assessing environmental pollution risk as of yet.

10.3 **Biohazard waste:** Due to the handling of infectious diseases, all laboratories aim to operate to at least a biosafety level II – including protocols for biohazard waste disposal – and staff are trained in relevant biosafety and biosecurity risk management.

10.4 **Water quality:** The Fleming Fund is a surveillance programme for antimicrobial resistance found in bacteria, often transmitted through poor quality water. As such, the programme can help to improve water quality and protect clean water resources from contamination through early detection of infection. Fleming Fund Fellows monitor antibiotic use and resistance in aquaculture and food production systems, and country grants help LMICs comply with relevant standards from the World Organisation for Animal Health (OIE) on the use of antimicrobial agents in aquatic animal species.

10.5 **Biodiversity and land degradation**: There are interlinkages between AMR and wildlife with the cross-over of bacterial species or genetic material, and there is increasing evidence that wildlife is a reservoir for antimicrobial resistance. Furthermore, this association is closely related to proximity to human activity or settlement, so the AMR surveillance programme may have an indirect effect on preserving biodiversity by reducing exposure to AMR risks in wildlife.

10.6 As AMR is a One Health issue, the Fleming fund works on environmental, animal, and human health surveillance to provide data and insight into the scale and scope of AMR and its drivers (such as antibiotic drug residues) in the environment. This, alongside other data generated by the Fund's investments, will act to enhance environmental stewardship.

10.7 The Fleming Fund has completed a climate risk screening tool (Annex H) and the level of risk posed by the programme's activities is assessed as low. The Fund will continue to monitor associated climate risks in accordance with the Green Finance Strategy.

11. Key Dependencies and Constraints

11.1 The Fleming Fund has considered the following key dependencies to be relevant on phase II of the programme:

- A country National Action Plan (NAP) for AMR developed with enough detail to establish Fleming Fund priority activities is critical. The Fleming Fund is separately funding the three multilateral organisations (WHO, FAO and OIE) to work with governments on developing their NAPs on AMR. The Fund has successfully supported the implementation of NAPs in the Fund's current 21 countries and plans to continue this support with future updates to NAPs.
- Political will to nationally accept data and use analysis to change health programming and policy – DHSC will continue to work, with FCDO and

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WHO/FAO/OIE offices in each country to ensure contact has been made with the right stakeholders within Ministries of Health and that they remain engaged. Ahead of working with a new country, the Fleming Fund team ask the AMR country leads and/or Ministry of Health colleagues to commit to sharing the data generated.

- The Global AMR Surveillance System (GLASS) continues to function and does not require additional obligations on those submitting data. Through the DHSC grant to the WHO, the Fleming Fund team is regularly in touch with the WHO team that lead on GLASS. As the Fleming Fund is the largest single financial commitment to AMR surveillance at present, the WHO GLASS team are eager to share information and support DHSC in this work. If any changes were to be considered, DHSC would be informed early on and would review to mitigate any risk to the programme.
- Sustainable investment and time commitment at country and global levels for tripartite grants and fellowships to function as anticipated. WHO/FAO/OIE must continue to prioritise AMR and national decision makers must allow fellows the opportunity to work on Fleming Fund activities to make a discernible difference.

11.2 The Fleming Fund recognises the following key constraints in phase II of the programme:

- Stability of the countries the Fleming Fund invests in cannot be mitigated and there is a risk that Fleming Fund investment countries suffer from a natural disaster, an outbreak of civil unrest or the un-controlled spread of an infectious diseases (as in the case of Ebola), all of which will impede or prevent progress on Fleming Fund activities. The Management Agent supplier has a business continuity plan in place for their work. This is a contractual obligation and can be reviewed annually by DHSC. This plan must include consideration of country stability and options to pause, terminate or reduce activities in country as a proportionate response. This must also include consideration of the safety of staff in the field and how this is ensured as the primary objective. DHSC will work closely with the FCDO Network in identifying political and environmental risks.
- COVID-19 has impacted many countries the Fleming Fund works with. Country grantees have adapted during phase I, progressing activities virtually where possible, however international travel restrictions have stopped international staff visits. New regional strains and vaccine rates averaging less than 10% indicate that further lockdowns and disruptions are likely. The Fleming Fund plans to adapt grant activities, payment schedules and forecasts where required and will include further mitigations in phase II plans.

12 Strategic Risks

12.1 The Fleming Fund maintains a programme level risk register and a country level risk register which are reviewed at quarterly Fleming Fund project board meetings. There is also a joint risk register with the Management Agent which is reviewed at quarterly review meetings between DHSC and the Management Agent (see Annex I), and risk registers between DHSC and all Fleming Fund partners where direct grants and contracts are in place. Collectively these risk

registers support effective programme management (more information available in section 13 of the Management Case).

12.2 **Strategic risk 1**: COVID-19 overwhelms already weak health systems. This could limit the programme's impact as healthcare workers and fellows are drawn into their country response to COVID-19 and have little time to focus on AMR surveillance.

- **Mitigation**: Fleming Fund work contributes to health system strengthening and supports pandemic preparedness in developing countries. This is done through developing diagnostic and laboratory capacity and flexing to support COVID-19 activities whilst achieving AMR aims. Collaboration with wider GHS activities mitigates this risk through increasing adherence to the International Health Regulations (IHR), and deployment of the UK Public Health Rapid Support Team.

12.3 **Strategic risk 2:** Fleming Fund country and regional investments in laboratory capacity, diagnosis and surveillance are not sustainable and do not constitute what has come to be understood as responsible aid programming. Given the focus on improving laboratory capacity, poor or unsustainable interventions could result in a considerable cost and resource burden on the target country to either continue funding or lay waste to the interventions.

- **Mitigation**: Sustainability is a key parameter for evaluation. The Fleming Fund has developed a strategy for sustainability, and is updating this for phase II, including ensuring grantees understand the political context within which they are working and are undertaking activities intended to secure longer term national investment to tackle AMR. Exit planning is also a key part of initial design of interventions in country. Although the UK has contributed to the development of AMR surveillance systems, LMICs have full ownership of their National Action Plans and country-specific strategic objectives that ensure their efficacy in the long-term. The Management Agent works with grantees to ensure country ownership of grants based on national priorities, create SMART objectives, capacity building for national stakeholders, and training and education through the fellowship grants. In making the economic case, the Fleming Fund also showcases the benefits to developing robust health systems by addressing AMR.

12.4 **Strategic risk 3:** The Fleming Fund's programme outcomes are not achieved, as collected and analysed data is not sufficiently shared or acted upon nationally, regionally, and globally.

- **Mitigation**: phase I grant activities have in part focused on ensuring that countries have functioning AMR Coordinating Committees (AMRCCs). These AMRCCs support the collection and analyse of data at the national level and facilitate sharing across sectors as well as regionally and globally. Grant activity in phase I has also supported countries to share this data globally through GLASS. Policy fellows have a particular role in ensuring data is acted upon nationally. The strategic shifts in phase II will move the focus form data collection and analysis to prioritising the use of this data.
- The Evaluation Supplier assesses prospects for the use of the data and provides recommendations for the programme to consider and adopt. The

Fleming Fund Technical Advisory Group (TAG), made up of senior industry experts, provides input from a technical perspective. The Fleming Fund team have developed an adaptive management workplan to ensure lessons learnt are adopted. The Fund's new areas of focus are targeted to strengthen the link between programme outputs and outcomes.

12.5 **Strategic risk 4:** UK investments through the Fleming Fund do not align with other international efforts to improve diagnosis and treatment of infectious diseases, in particular AMR, laboratory capacity and diagnosis for priority pathogens. As AMR moves up the international agenda, poor alignment could mean duplication of work, contradiction of priorities, and a disconnect with national and local stakeholders engaging with different donors.

- **Mitigation**: A desk-based and in-country assessment and positioning exercise was carried out to map the AMR, infectious disease and laboratory strengthening landscape to avoid duplication and explore alignment and synergies ahead of investment. With country grantees now in place, the Fleming Fund has a much clearer understanding of other national and international efforts on AMR in each of the Fund's 21 countries. The Fund continuously consults and coordinates with key donors and stakeholders, in particular global organisations, NGOs, and national aid agencies.

12.6 **Strategic Risk 5**: There is a risk that grantees engage in fraudulent activity or corruption at all levels of Fleming Fund grants, irrespective of size and nature.

- **Mitigation:** The Fleming Fund have carefully assessed the risk of fraudulent activity and necessary financial monitoring in section 6 of the Financial Case.

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Economic case

1. Introduction

1.1 Since the 2017 business case (FBC) and the BC extension in March 2021 there have been three main developments that further strengthen the economic case for investment in the Fleming Fund. Firstly, there is new evidence on the global burden of AMR (see section 5.1-5.3 of the Strategic Case for more); secondly, there is new evidence on the costs and benefits of AMR surveillance (see sections 14-15 of the Economic Case); and finally, there is new evidence on the probability of successes based on the project's performance to date (see section 3 of the Economic Case). This new evidence and data have supported the construction of a Comprehensive Investment Appraisal (CIA) which forms the basis of this Economic Case.

2. Evidence on Human Cost of AMR and its drivers

2.1 Previous Fleming Fund business cases deployed extensive evidence on the global economic and human cost of AMR from the World Bank and Lord O'Neil's AMR Review, including:

- Antimicrobial resistance (AMR) is a 'silent pandemic', predicted to worsen killing 10m people a year globally by 2050[24].
- The cost to the global economy of unchecked AMR will include:
    - $100 trillion in cumulative global cost by 2050[25]
    - 3.8% of global annual GDP by 2050, with an annual shortfall of $3.4 trillion by 2030[26]24m people forced into extreme poverty by 2030, threatening achievement of the SDGs.[27] (see section 2 of the Strategic Case for more)

2.2 However, the global burden of AMR is worse than previously imagined, with just under 5 million deaths associated with AMR in 2019[28] (see section 5.1-5.3 of the Strategic Case for more). Putting resources into stopping AMR is one of the highest-yield investments any country can make, with an estimated return on investment of between 31% and 88% annually.[29]

3. New evidence on the success of the programmes

3.1 There is newly aggregated evidence on both the quality and effectiveness of the Fleming Fund activities to date and linked outputs (see section 4 and section 5 of the Strategic Case) – which provides a strong indication that these will translate into the desired outcomes and impact. The Independent Evaluation, successive

[24] The Review of Antimicrobial Resistance, Tackling Drug Resistant Infections Globally, (2016)
[25] *Idem*. P.15
[26] World Bank, Drug Resistant Infections, A Threat to Our Economic Future, P.19 (2017)
[27] *Idem*. P.20
[28] Global Research on AMR (GRAM) project, Global burden of bacterial antimicrobial resistance in 2019, Institute for Health Metrics and Evaluation/University of Oxford (2021)
[29] World Bank, Drug Resistant Infections, A Threat to Our Economic Future, P.19 (2017)

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Annual Reviews, and ongoing monitoring (via a comprehensive monitoring framework) have found that the majority of grants are on track to deliver intended outcomes (see 4.10-4.11 of the Strategic Case and Annex D).

3.2 At the output level, the project has been successful in increasing the core capacity of countries human health and animal health laboratories as measured against the London School of Hygiene and Tropical Medicine Roadmap – a core indicator for the success of the programme included within the original FBC. (See figures 1.6 and 1.7 of the Strategic Case). The LSHTM Roadmap provides a way of assessing core surveillance capabilities and assigning countries a rating against common criteria (See figure 1.10 of the Strategic Case). The evaluation has found evidence of data sharing and that the management agent is working toward effectiveness.

4. Current position of the program

4.1 The programme is at around the midpoint of its originally intended duration given delays with commencing implementation, and due to the impact of COVID-19 more recently. The original business case noted that there would need to at least one further phase of investment to realise the project's potential, this was reflected in the 5+5-year structure of the associated Management Agent contract.

5. Spending objectives (SOs)

5.1 The spending objectives are utilized in the options appraisal of the long and short list. These objectives can be found in section 6.1 of the Strategic Case. The Strategic Case also offers the rationale for supporting the chosen objectives. The objectives have been linked to corresponding benefits in section 10 of the Economic Case.

6. Critical success factors (CSFs)

6.1 Critical Success Factors" (CSFs) are the attributes that any successful proposal must have, if it is to achieve successful delivery of its objectives. The HMT Green Book advises that the following CSFs should form part of any proposal.

1. Strategic fit and meets business needs
2. Potential Value for Money
3. Supplier capacity and capability
4. Potential affordability
5. Potential achievability

7. Qualitative options appraisal

7.1 **Long list of options:** The long list of options considered at the FBC 2017 is listed within Annex K. This list remains valid, given the context:

- Funding has already been agreed in principle by HMT and Ministers for the Fleming Fund (AMR surveillance) / GHS programme as part of the Spending Review 2020 proposals.

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- That re-opening the long-list to consider other (non-surveillance) AMR interventions would be an artificial exercise – given the ongoing need for investment in surveillance as set out in the original business case.

7.2 This long list of options has been retrospectively broken down into the various components of the options framework. This was done to demonstrate that a full and complete list of options has been considered and that the most appropriate options where then shortlisted.

7.3 **Short list options appraisal:** From the long list of options, the following short list has been selected. Figure 2.1 breaks these options down into the various options framework categories. The analysis of these options against the case's CSFs has also been included in figure 2.2.

- Option 0: Do nothing counterfactual[30] (Business as Usual in Green Book terms) - this option stands as the counterfactual and considers the implications of not funding the program. This option fails CSFs 1,2.
- Option 1: Hub and spoke model delivered through charitable foundation or research council. This option considers designing the Fleming Fund country and regional programme in collaboration with a UK based charitable foundation or research council such as the Welcome Trust or the Medical Research Council which work in the field of biomedical sciences with considerable presence in LMICs. This partnership could involve some form of financial contribution from the relevant organisation and commitment of resources to support the programme.
- Option 2: Hub and spoke model delivered through new Management Agent (MA). This option explores selecting a private sector/non-governmental Management Agent to deliver the Fleming Fund portfolio of country and regional investments. Much like option 1 this would employ a hub and spoke model where one delivery partner, identified through open competition, then runs calls for funding and executes all required grant management of downstream grantees in a number of different countries and regions. This option explores selecting a new Management Agent via a competitive process. This would be aimed at seeking improving MA performance/ efficiency and/or reduced MA costs.
- Option 3: To directly identify and manage a portfolio of country and regional investments. This option explores the DHSC team's capacity in directly design the Fleming Fund call for funding, engaging with the supplier market in a selection of countries, evaluating bids, and managing and monitoring the resultant grants for the full funding period.

[30] The minimum specification option is to do nothing. Given the scope and scale of the problem targeted (a lack of AMR data at national, regional, and global level - linked to a fundamental lack of capacity in LMICs) it is not feasible to offer a scaled down version and expect to deliver meaningful results at global level. For this reason, the Fleming Fund consider the only feasible alternative is to do nothing (creating operational space for other actors to step in in the longer term).

- Option 4: Hub and Spoke Model delivered through existing Management Agent.

8. Options framework categories

8.1 The options framework categories recommended by HMT's Green Book are scope, solution, delivery, implementation, and funding. Figure 2.1 considers each option against each of these categories to understand if, and how, it could deliver the desired service.

Figure 2.1: Options framework categories

Category	Option 0	option 1	Option 2	Option 3	Option 4
Scope *coverage of the service to be delivered*	Not applicable	mplemented across Low- and Middle- Income Countries			
Solution *how this may be done*	Discontinue current and future operations	Strengthen national surveillance systems, strengthen enabling environment, provide data, analysis and reporting of the data gathered.			
Delivery *who is best placed to do this*	Discontinue current and future operations	Delivered and managed by a charitable foundation or research council.	Delivered and managed by a new private sector management agent following competition.	Delivered and managed by DHSC directly.	Delivered and managed by existing management agent.
Implementation *when and in what form can it be implemented*	Discontinue current and future operations	Continuation of existing services but via a new NGO/Health Foundation.	Continuation of existing services but via new agency	Continuation of existing services but via DHSC	Continuation of existing supplier/service
Funding *what this will cost and how it shall be paid for*	Discontinue current and future operations	Fleming fund to provide main body of nvestment. Possible financial contribution from the delivery partner.	Fleming fund provides total funding.		

8.2 The assessment of the short list of options against the CSFs and SOs has been summarised in figure 2.2 below. A full breakdown has been provided as an appendix to the case which assesses each option against individual CSFs and SOs (see Annex K).

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8.3 The following table assesses each option against the Critical Success Factors in the context of each of the framework categories.

Figure 2.2: Assessment against CSFs

Category	Option 0	option 1	Option 2	Option 3	Option 4
Scope	Fails CSFs 1 and 2	Meets all CSFs			
Solution	Fails CSFs 1 and 2	Meets all CSFs			
Delivery	Fails CSFs 1 and 2	CSFs 3, 4 and 5 are only partially met	Meets all CSFs	CSFs 3, 4 and 5 are only partially met	Meets all CSFs
Implementation	Fails CSFs 1, 2 and 5	SO's 1-3 and CSFs 1 and 2 only partially met			Meets all CSFs
Funding	Fails CSFs 1 and 2	Fully meets all CSFs except for CSF 3 which is only partially met	Meets all CSFs		

9. Compiled short list of options

9.1 **Preferred option:** The short list options appraisal concludes that option 4, as described in section 7.3, is the preferred option. Among all short list options, it performs best when assessed against the CSFs and SOs of the case (fig. 2.2).

9.2 **Do minimum:** Due to the scale of the challenge[31], it is not feasible to fund an option with significantly different costs to that set out in the preferred option. Meaning any Do minimum option would be artificial. For this reason, a do minimum option has not been included in the short list.

10. Quantitative Analysis

10.1 The Comprehensive Investment Appraisal (CIA) model is a key appendix that supports the quantitative analysis (see Annex J).

[31] Given the scope and scale of the problem targeted (a lack of AMR data at national, regional, and global level - linked to a fundamental lack of capacity in LMICs) it is not feasible to offer a scaled down version and expect to deliver meaningful results at global level.

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11. New evidence on the costs and benefits of AMR surveillance

11.1 Since the last FBC was submitted, the Fleming Fund has significantly increased general understanding of the costs and benefits of establishing AMR surveillance systems in Africa and Asia due to critical new literature (see paragraph 13 and 14 below) and a Cost Benefits Framework pilot commissioned by the Fleming Fund.

11.2 Evidence that has been highlighted by previous business cases but remains relevant includes, the 2016 Commission on a Global Health Risk Framework for the Future and the O'Neill Review on AMR. These recommended an annual investment of around US$4.5 billion to address the risk pandemic diseases pose. The UK government has invested more than £615m in tackling drug-resistant infections since the government launched its national strategy at the end of 2013.

11.3 The costs of global surveillance can be allocated across regional, global, and national level structures. The cost analyses below focus on country level costs primarily which depends on national data requirements, priorities, and capacity.

12. Uganda case study

12.1 The cost benefits framework has provided a comprehensive account of the total costs of establishing, equipping, and running a human and animal health AMR surveillance system in Uganda, including quality assured bacteriology capabilities and a range of epidemiological, clinical, veterinary, and policy and evaluation functions. It suggests that the total costs would be in the region of £2m per year for a system which includes 19 fully supported laboratories. This system could process up to 220-250,000 samples annually. Currently these costs are funded by the Ugandan Government and a mix of donors including the Fleming Fund (contributing about £800,000 per year, including management agent costs). The total costs are relatively low as the AMR surveillance piggybacks off existing infrastructure, governance, and laboratory systems wherever possible. This indicates that the newly embedded system is both broadly affordable and carries prospects for sustainability. The Framework has also generated a prospective list of benefits (see Annex L).

13. Kenya case study

13.1 The World Bank finds that "The cost of AMR surveillance per se will be a relatively modest add-on to existing laboratory costs, when built on an established national network of well-functioning clinical laboratories[32]." They base this on an assessment of the cost of managing AMR surveillance in Kenya. The World Bank Estimate that based on current expenses in Kenya, establishing and running a (human health) AMR surveillance network with eight well-functioning satellite (or county) laboratories will cost about $160,000 USD per

[32] CDEEP, Strengthening the Role of Laboratories in Tracking Antimicrobial Drug Resistance in East Africa, p 12. (2016)

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year. This follows an initial investment of around $2m dollars. This supports an assessment of AMR surveillance as having a “modest” cost in an LMIC setting.[33.]

14. South East Asia case study

14.1 A new study in *Global Public Health* provides a conservative estimate of the costs for setting up and running a microbiology laboratory for AMR surveillance in South East Asia. The study indicates that establishing a laboratory with the capacity to process 10,000 specimens per year ranged from $254,000 to $660,000 while the cost for a laboratory processing 100,000 specimens ranged from $394,000 to $887,000. Excluding capital costs to set up the laboratory, the cost per specimen ranged from $22–31 (10,000 specimens) and $11–12 (100,000 specimens). The cost per isolate ranged from $215–304 (10,000 specimens) and $105–122 (100,000 specimens).

14.2 It notes that in the absence of donor support, these costs may be prohibitive in many low- and middle- income country (LMIC) settings. With the increased focus on AMR detection and surveillance, the high laboratory costs highlight the need for more focus on developing cheaper and cost-effective equipment and reagents so that laboratories in LMICs have the potential to improve laboratory capacity and participate in AMR surveillance.[34]

15. Case Study Conclusion

15.1 New evidence on costs and benefits from Kenya, Uganda and South-East Asia strengthen the economic case for intervention. They demonstrate overall costs are relatively modest from a high-income country perspective – particularly given the wide-ranging benefits. They also serve as a reminder that AMR surveillance remains broadly unaffordable from many LMICs’ perspectives. This creates a case for donor intervention in underlying AMR infrastructure.

15.2 However, there remain substantial gaps in the available knowledge, including in quantifying the benefits of AMR surveillance in LMICS, as much of this can only be captured as Fleming Fund AMR surveillance systems mature. This will require additional investment by the Fleming Fund in supporting roll-out of the cost benefits framework.

16. Programme Costs

16.1 The programmes approach to managing costs is to assume an upper ceiling and then manage risks to overspend by reducing planned activity. This approach transfers cost implications into benefit realisation. This approach is possible given the large number of grants that can be flexed and provides some

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[33] It is noted that the Fleming Fund multi-year investment’s in Kenya cover a greater number of sites, as this includes animal health also, with a greater initial outlay linked to the need to upgrade these labs and support stronger governance across sectors also.
[34] Global Public Health, Antimicrobial resistance detection in Southeast Asian hospitals is critically important from both patient and societal perspectives, but what is its cost? (October 2021)

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confidence that the requested grants will be spent without overspend. With a single possible risk exception set out in section 15. Each of the short list options is expected to have the same level of cost apart from option 1 as set out in section 7 above, which will see a £10 million reduction in revenue cost. This is the result of a not-for-profit Management Agent (i.e., charitable foundation or research council) being used leading to a reduction in fees.

17. Optimism bias

17.1 The term ‘optimism bias is used in the Green Book as a measure of optimism in project estimates**.** The Fleming Fund’s first phase included over-optimistic estimates of the time that it would take to mobilise regional hubs, secure government support and complete grant competitions. This resulted in a delay of about 12 months to overall implementation which was compounded by an extended inception (design phase) and then COVID-19.

17.2 The programme has now experienced several grant lifetime cycles and has better data to inform estimates linked to these activities. The Fleming Fund therefore would judge the risk of optimism bias to now be lower.

17.3 The Fund assumes an optimism bias of around 20% based on four years of forecasting / costing information.

18. Programme Risks

18.1 A detailed risk register has been developed which includes quantitative assessments of the probabilities and impacts of various program risks (see Annex M). As stated, the programme follows a costing model whereby any increase in cost would instead be reflected as a reduction in activity and therefore lead to reduced outcomes and benefits of the program. This transfers the impacts of most risks to a benefit reduction. Such changes are instead reflected in the sensitivity analysis.

18.2 However, there is a risk of increased staffing requirements that does have cost implications that cannot be transfer to benefit reduction. The program relies heavily on FCDO to liaise with the governments of LMICs in which the Fleming Fund operates [redacted]
[redacted]
[redacted] The extended cost of this is reflected in risk K1. The calculation of this risk is explained further in the CIA model risk log.

19. Monetisable Benefits

19.1 There are a range of sources to pull from that discuss the impacts of AMR. These sources provide a strong rationale for intervention. However, whilst the qualitative argument for intervention is clear, quantifying the aforementioned effects of AMR interventions and apportioning them to specific investments is much more complex. The data to allow for this quantification and apportionment is therefore less prevalent. This makes monetising the impacts of any specific investment such as the interventions proposed by the Fleming Fund more difficult**. This means that a top-down benefit calculation is currently possible, but a bottom-up benefit calculation is not.**

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19.2 The monetised benefits of the case are calculated by first analysing the impacts of global AMR interventions, for which there is more data. This generated a total global benefit of all AMR interventions over the appraisal period. The following adjustments were then made to scale the projected benefit to the Fleming Fund's surveillance investment.

- A 50% reduction to account for other investments required to deliver the benefits.
- A 25% reduction to account for the portion of the benefit that can be delivered entirely without AMR surveillance.
- A 50% reduction to account for the shifting Return on Investment (ROI) depending on the stage of total AMR prevention investment this intervention represents. This reduction is arbitrary. However, it is considered to make the benefit more conservative.
- These adjustments, the rationale behind them and the figures produced are all explored in more detail in Annex L.

19.3 Two benefits have currently been monetised. The first is related to avoided health expenditure required to combat AMR in the absence of preventative measures. The second is an avoided loss of GDP. Both are based on figures quoted in the World Bank 2016 paper on drug resistant infections.

19.4 The latter of these benefits would incorporate effects which are already accounted for by HMT at a national level. Including the benefit, as part of the Benefit Cost Ratio (BCR) calculation, would therefore constitute a double count. However, the significant magnitude of this benefit should be considered when assessing the VfM of each option.

19.5 Figure 2.3 shows a breakdown of the global benefits of AMR surveillance by year for low and high AMR scenarios, as well as an expected scenario. The expected scenario in conjunction the costs has been used to calculate a Benefit Cost Ratio (BCR) in the CIA. The global costs and benefits have also been adjusted to reflect 2022 prices in line with the base year. These benefits have then been reduced in variety of ways to reflect each shortlist option, see Annex L for more detail.

Figure 2.3 Breakdown of global benefits over the next five years £m

Scenario	Benefit	2022	2023	2024	2025	2026	Total
High AMR	Global output	£81,720	£168,362	£260,010	£356,807	£458,866	£1,325,765
	Health impact	£21,461	£42,921	£64,382	£85,843	£107,303	£321,910
Low AMR	Global output	£27,527	£56,711	£87,582	£120,188	£154,565	£446,574
	Health impact	£4,769	£9,538	£14,307	£19,076	£23,845	£71,536
Expected scenario	Global output	£54,624	£112,537	£173,796	£238,497	£306,716	£886,169
	Health impact	£13,115	£26,230	£39,345	£52,459	£65,574	£196,723

20. Qualitative benefits

20.1 The following figure 2.4 lists a variety of benefits linked to AMR surveillance. It should be noted that these benefits are not necessarily separate from the monetised benefits of the case. For many of these benefits it is simply that they cannot be disaggregated from the larger benefit calculation. This should be kept in mind when assessing the wider VfM of the cases options.

20.2 The benefits are felt across human and animal health, at global, national, and sub-national level. The "high level" benefits apply to the Fleming Fund as a whole and were identified as part of the development of the Theory of Change. Ultimately, the Fleming Fund expects to see a reduction in death and morbidity, countries will also see reduced costs for health and agriculture systems associated with optimisation of drug use.

Figure 2.4 Benefits linked to AMR surveillance

Benefit		Sub-benefit		Linked Spending Objective (SO)
1. Facility				
1.1	Information to guide antimicrobial treatment when laboratory results are analysed regularly and communicated to clinical staff.	1.1.1	Reduced burden of disease: improved prescription of antibiotics and antibiotic stewardship should lead to better clinical outcomes and DALYs averted (better guided treatment, decrease in AMR infections)	**Objective 2**: improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
		1.1.2	Reduced cost: less time in hospital, less time out of work for patient and their carers, more cost-effective treatments prescribed (i.e., less prescription of antimicrobials)	**Objective 1**: strengthen national AMR surveillance, laboratory, and workforce capacity in up to 25 priority countries.

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1.2	Early detection of outbreaks of particular AMR strains or hospital-acquired infections generally.	1.2.1	Improved infection control, reduced burden of disease should lead to DALYs averted	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
		1.2.2	Reduced cost: less time out of work for patients and their carers, less cost to patient and health system than if big outbreak	**Objective 1**: strengthen national AMR surveillance, laboratory, and workforce capacity in up to 25 priority countries.
1.3	AMU data used to improve use of antimicrobials at site level	1.3.1	Better antimicrobial stewardship and likely reduction in drug budget	**Objective 1**: strengthen national AMR surveillance, laboratory, and workforce capacity in up to 25 priority countries.
2. National				
2.1	Information to update standard treatment guidelines – evidence based public health policy	2.1.1	High/increasing rates of resistance to first-line antibiotics by specific pathogens are confirmed and made known to policy makers	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
		2.1.2	Policy makers revise treatment guidelines and associated essential medicines list (EML) in accordance with the evidence	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.

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2.2	Information to update guidelines for AMU in animals	2.2.1	Policy changes to stop usage of particular antibiotics in animals (i.e., where there is high resistance)	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
2.3	Information to track trends in AMR, including geographic variations and links between human and animal AMR.	2.3.1	Information can be used to establish and evaluate targets for AMR reduction	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
		2.3.2	Set priorities for research	**Objective 2**: improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
		2.3.3	Design and evaluate public health interventions (e.g., based on AMU survey information – look how this impacts on AMR)	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
		2.3.4	Influence industry practice	**Objective 3**: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.

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		2.3.5	Information can be used for national campaigns and AMR awareness.	**Objective 2**: improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
3. Global				
3.1	Promote understanding of AMR in each country compared to global patterns; helps complete global picture.	3.1.1	International benchmarking (standardised usage of antimicrobials between countries).	**Objective 2**: improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
3.2	Mitigate against impact of AMR pandemic	3.2.2	Inform public health interventions to prevent diseases where AMR is a significant problem.	**Objective 2**: improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
4. High Level Benefits - *Identified as part of the development of the Theory of Change*				
4.1	Increased One Health AMR microbiology laboratory capacity and surveillance systems.			**Objective 1:** strengthen national AMR surveillance, laboratory, and workforce capacity in up to 25 priority countries.
4.2	Upskilled in-country staff with the right training, equipment, and systems to gather, analyse and share quality AMR data for their country.			**Objective 1**: strengthen national AMR surveillance, laboratory, and workforce capacity in up to 25 priority countries.
4.3	Functioning in-country AMR governance and leadership mechanisms such as AMR National Coordinating Committees (AMRCC) or equivalent, and technical working groups.			**Objective 3:** increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create

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c4.3		stronger, more resilient, and integrated health and food production systems.
4.4	Improved awareness and understanding of the threat among key surveillance stakeholders to ensure countries are convinced of the need for action.	**Objective 3:** increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
4.5	Increased generation of quality AMR, AMU/AMC data, data on the burden of disease, and data on quality of medicines across One Health domains.	**Objective 3:** increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
4.6	Increased analyses of quality data at country, regional and global levels to produce trends and statistics that are relevant, meaningful, and insightful, having utility to form policy and practice.	**Objective 2:** improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
		Objective 3: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
4.7	Increased quality AMR, AMU/AMC data shared with a wide range of stakeholders nationally and globally via agreed AMR governance mechanisms.	**Objective 2:** improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.

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c4.7		**Objective 3:** increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
4.8	Decision makers at facility, national and global level, convinced of the need for action.	**Objective 2:** improve global understanding of the threat of AMR by providing quality AMR/C/U evidence for global advocacy and policy.
		Objective 3: increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems.
4.9	Increased political space within which new policies, processes, governance, and budgets to tackle AMR are created.	**Objective 3:** increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems
4.10	Decision makers use quality data for evidence informed health policy and programming.	**Objective 3:** increase awareness and the use of AMR and antimicrobial usage data to change policy and practice and create stronger, more resilient, and integrated health and food production systems

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21. Sensitivity analysis

21.1 The sensitivity analysis is broken into two sections. The first section looks at "**switching values**" or how different options would be affected by a shift in costs or benefits. This also identifies the point at which the preferred option could change given a reduction in benefit or increase in cost. The second section is **scenario analysis** which shows various scenarios that might lead to changes in costs and benefits. The effects of these scenarios are shown as changes to BCR values.

21.2 Switching values

21.2.1 Figure 2.5 shows the change in revenue, capital and benefits required to potentially change the preferred option. For example, it shows that option 2's revenue cost would have to decrease by 8.36% for option 2's BCR to equal that of the preferred option. In the case of option 4 (the preferred option) it is showing the change in costs and benefits required to shift option 4's BCR to equal that of the second-best option (option 2), when assessed purely on BCR values.

21.2.2 Whilst you may note the small changes required to alter the options ranking, particularly between options 2 and 4, the vast majority of possible reasons that might lead to cost and benefit changes are expected to affect each option in a similar manner. Furthermore, option 4 performed most favourably when assessed qualitatively in section 8. This is to say that despite the comparably similar BCR values of options the options ranking is considered suitably robust for the aforementioned reasons.

Figure 2.5: Cost/Benefit adjustment of options

Cost/Benefit adjustment	Option 1	Option 2	Option 3	Option 4
	% change			
Required change in revenue cost	-13.94%	-8.36%	-12.11%	9.03%
Required change in capital cost	minus more than 100%	-68.54%	-99.26%	74.04%
Required change in Benefits	14.24%	8.03%	12.07%	-7.44%

21.3 Scenario Analysis

21.3.1 Figure 2.6 describes various scenarios and the likely impacts on the short list of options. This analysis concludes that while various scenarios might alter the BCR of options, they ultimately are not likely to result in an unacceptably low BCR or change in the options ranking. Fig 2.6 shows that option 4 is the least negatively impacted of all options (Apart from Option 0, BAU) under each of these scenarios and would remain the preferred option.

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Figure 2.6: Scenario analysis and impacts on short list of options

Scenario 1: COVID-19 affecting implementation in Fleming Fund countries, case numbers still having significant effect. This might make it harder to operate in these countries creating an underspend.
Option 0 - **Moderately affected -** under this scenario, the Fleming Fund would expect COVID-19 to exacerbate AMR risk – through reducing domestic and global resources - and potentially in some countries (though not all) increasing the use of antibiotics in healthcare settings. If the COVID pandemic seriously worsened to the extent that it resulted in grants being operationally non-functional then Option 0 could become the most favoured.
Option 1 - most affected – the new 'management agent' would have no previous experience of managing/adapting the programme to COVID-19 with an impact on their ability to support change-management. **Under this scenario option 1, 2 and 3 would be most impact and less favoured than option 4.**
Option 2 - most affected - the new 'management agent' would have no previous experience of managing/adapting the programme to COVID-19 with an impact on their ability to support change-management. **Under this scenario option 1, 2 and 3 would be most impact and less favoured than option 4.**
Option 3 - most affected - the new 'management agent' would have no previous experience of managing/adapting the programme to COVID-19 with an impact on their ability to support change-management. **Under this scenario option 1, 2 and 3 would be most impact and less favoured than option 4.**
Option 4 – least affected – The existing management agent will be best placed to adapt the programme to any further COVID-19 waves – having previously overseen the adaption of the programme and improved performance. **Under this scenario option 4 would remain the preferred option** – even with some impact from COVID-19.
Scenario 2: Reduced delivery of benefits for a variety of reasons: underspend on forecasts lead to HMT reducing funding, delays in delivery against implementation plan and the majority of spend remains as management agent fees.
Option 0 - **least impacted by this risk**. This option would be preferred subject to very strong evidence that value for money could not be achieved. However, this scenario is a low possibility.
Option 1 - Most impacted by this risk – will have least direct experience of managing mid-year reductions in spending. It is likely that this option would be able to contain management fees better than option 2. **This option and 2,3 would be least preferred under this scenario.**
Option 2 - Most impacted by this risk - Most impacted by this risk – will have least direct experience of managing mid-year reductions in spending. **This option and 1,3 would be least preferred under this scenario.**

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Option 3 - most impacted by this risk - Most impacted by this risk – will have least direct experience of managing mid-year reductions in spending. **This option and 1,2 would be least preferred under this scenario.**
Option 4 - moderately impacted by this risk - the management agent has experience of adjusting grant envelope mid-year while maintaining impact of entire grant portfolio.
Scenario 3: Management agent does not have the required expertise, capacity, and capabilities to deliver the scheme, or there is a lack of necessary staff for scheme delivery.
Option 0 - Zero impact – this option would not be affected by this scenario.
Option 1 - moderately impacted – the new managing agency would need to mobilise from scratch and so be at risk of not being able to secure staff.
Option 2 - moderately affected - the new managing agency would need to mobilise from scratch and so be at risk of not being able to secure staff.
Option 3 - least impacted - DHSC would likely have least flexibility in terms of its recruitment strategies being constrained by CS HR and the lack of an existing staff network/platform in the four regions in which the programme operates. **This option would be least preferred under this scenario.**
Option 4 - most impacted – The existing management agent has an existing complement of staff with suitable skills/experience and has experience in securing staff in all four regions with the requisite experience. **This option would be most preferred under this scenario.**
Scenario 4: Fleming Fund investment results in harm to vulnerable communities and or investments are not sustainable in the long run.
Option 0 - Least affected as no FF investments to generate harm / exposed to risks of unsustainability
Option 1 - Most affected/equally affected – the management agency under this scenario does not have an existing sustainability plan which could be used to mitigate this risk. **Options 1,2,3 are equally not preferred under this scenario**
Option 2 - Most affected/equally affected - the management agency under this scenario does not have an existing sustainability plan which could be used to mitigate this risk. **Options 1,2,3 are equally not preferred under this scenario**
Option 3 - Most affected / equally affected - the management agency under this scenario does not have an existing sustainability plan which could be used to mitigate this risk. **Options 1,2,3 are equally not preferred under this scenario**
Option 4- Moderately Affected – under this scenario the management agent with most experience/an existing sustainability plan, is likely to be able to anticipate/develop mitigations to the risks of harm/unsustainability considered by this scenario.

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Scenario 5: Benefits are not accurate due to differentiation of LMICs AMR surveillance ROI compared to global ROI. Or incorrect modelling of the stage of investment the intervention is attributed to.
Option 0 No impact
Options 1, 2, 3 and 4 Modelling of the benefits has been calculated as Return on a global scale. If the LMICs within the Fleming fund are impacted by AMR in a way that is significantly removed from the global this might lead to a very different BCR. Similarly, it is assumed in the benefit calculation that the investment has a reduced return on investment. That the marginal return would increase with further investment. It is possible the arbitrary adjustment made is not significant enough to account the lower initial ROI. However, the program considers the benefit calculation to be conservative and therefore more likely to increase rather than decrease. In part due to the assumed high level of global surveillance cost. Additionally, the World bank 2016 paper on drug resistant infections concluded that LMICs are likely to be most affected by AMR, which indicates the benefit maybe higher than estimated. Furthermore, no reasons have been identified that might lead one option being affected by this differently than another, meaning the options ranking would not change. The calculated worst-case scenario for the preferred option is a BCR of 0.76. Whilst this is lower than the 'target' BCR used by DHSC (4). The scenario is not considered to be likely, nor does it take account of the qualitative benefits of the investment.
Combined Scenario: The result of all scenarios occurring at once. Worst and best case.
With the exception of scenario 3 option 4 is always the least or an equally effected option under each scenario, setting aside the BAU. This means that under none of the above scenarios or combinations of is it expected that the preferred option would change. The scenario that delivers the highest VfM for the preferred option would be the high AMR scenario predicted by the 2017 World bank drug-resistant infections paper. Combined with the lowest predicted cost (currently an arbitrary estimate) leading to a BCR of 30.86. The expected worst-case scenario for the preferred option would be highest cost and lowest AMR scenario leading to a BCR of 0.76. These two estimates are the extremes, and neither are considered likely. Due to the various reductions made to the central estimate the final preferred option's BCR (4.19) is considered to be conservative. When this is considered in combination with unmonetizable factors it seems reasonable to state that neither the options ranking nor VfM of the preferred option appears to be significantly threatened.

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22. Conclusions

22.1 The Economic Case draws on a much stronger data set and a wealth of evidence to support the case for investment than existed at the point of the first business case in 2017. It explores in detail a variety of options to address the case's spending objectives and uses a model to demonstrate that the preferred option offers the best value and achieves a high Benefit to Cost Ratio of 4.19.

22.2 Given the relative novelty of this intervention, there is a level of uncertainty surrounding the options benefit calculations, there is an acceptable margin for error given the considerable unmonetized factors to be considered. This is also supported by a sensitivity analysis which concludes that the options ranking is robust. Despite the amount of uncertainty within calculations, the benefits of the preferred option exceed the 'target' BCR of 4.

22.3 Figure 2.7 shows the headline outputs of the CIA model including the final adjusted BCR values for each option. Whilst there is a small margin between the BCR of many options – we believe the case for recommending option 4 remains compelling given the current position of the programme and its successful track-record.

22.4 The Fleming Fund recognises the lack of data confirming the long-term benefits of AMR surveillance in LMICS and will commit to rolling out a cost

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benefits framework across targeted to countries to evaluate this further. The proposed strategic shift into economic data will further strengthen the evidence base. Both the qualitative and quantitative elements of the economic case support the VfM of this intervention, confirming the preferred option as the optimal way forward.

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Commercial Case

This section sets out the commercial approach to contracts and grant agreements across the five categories of investment set out in the investment pyramid in the strategic and financial cases.

1. Commercial Approach – Management Agent (70-75% of funding)

1.1 The current Management Agent (MA) Mott MacDonald, representing the vast majority of the Fleming Fund's overall expenditure, was appointed through a competitive tender in 2016 in compliance with UK and EU procedures for public sector procurement. Mott MacDonald (MM) was the lead partner in a consortium.

1.2 The original contract ran for five years (from Oct 16-Oct 21) with a built-in option to extend for up to a further five years at a similar scale of funding to the original requirement (i.e., £50-75m per year). The Investment Committee previously agreed an initial extension until March 2023 (at no additional cost), following the one-year SR settlement the Fleming Fund received for 2021-2022. If DHSC chooses to extend this contract the latest point it could be extended to is October 2026.

1.3 This section recommends renegotiating the terms of the contract with Mott MacDonald to ensure there is sufficient focus on outcomes in phase II. If successful, the contract could be extended until up to October 2026. The Fleming Fund project team propose an extension to March 2026 with the inclusion of a break clause in March 2025 which could be employed if further funding was not secured in the next Spending Review period.

1.4 The Fleming Fund team have determined that the Fund will continue to need to buy in the services of a Management Agent as DHSC is not appropriately resourced or located to directly manage a large international portfolio of country grants. The Fleming Fund requires an external supplier with an ability to operate in up to 25 priority countries and monitor and engage large numbers of downstream grantees, including national academic institutions, not-for-profits, and international development companies. The programme requires a strong approach to grant and programme management and experience of successfully delivering ODA-funded programmes of this complexity and scale.

1.5 The Fleming Fund's Management Agent for the first phase of the programme, Mott MacDonald, is very well positioned to continue to deliver this work. It took considerable time in the first 5 years of the programme to build delivery capacity across the current 21 priority countries, including: setting up 4 regional offices; hiring a full complement of 70+ technical and programme staff at HQ and in regional offices; and building networks and relationships with grantees and national authorities.

1.6 Mott MacDonald has met all contractual obligations over phase I. Although delivery in earlier stages was a concern, positive steps were taken to rectify this, for example by introducing a new Programme Director and more rigorous monitoring, and the organisation has since delivered well – see key successes in paragraphs 4.9-4.12 of the Strategic Case. They have achieved their KPIs, even as these have become more stretching over the course of phase I with the inclusion of KPIs on Global AMR Surveillance System (GLASS) and a measurement of the quality of data being provided. They have been responsive to feedback and undertaken adaptive management throughout, for example

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implementing changes to the Country Grant 2 process, supporting the Fund's COVID-19 flex in the regional whole genome sequencing grant, improving the approach to financial management and coordinating with other Fleming Fund partners to ensure alignment at country level. Commercially although overall fees have increased in accordance with contract terms, in order to add roles that DHSC and the Management Agent agreed were required to deliver the project more effectively, Mott MacDonald's value for money offer to DHSC and profit margins have stayed the same.

1.7 This is now a critical point in the programme where some country grants have only recently been initiated, for example in India. Terminating the contract ahead of phase II would cause a significant time lag for delivery and undermine the relationships built up in-country and with wider partners.

1.8 Critical for phase II will be a focus on moving from delivering outputs to delivering outcomes, particularly data use by countries . Failure to achieve these deliverables within 6 months of the agreed deadline results in the supplier losing the associated payment. The key KPI used to date has been an improvement in the reporting of data to GLASS by Fleming Fund supported countries. By linking payment to such targets, the Fund is sharing the risk of not achieving its intended outcomes. However, this is only one element of the wider Theory of Change for the programme, and it has been challenging to monitor the MA against wider outcomes through phase I. Broadening this performance framework to ensure they are contracted and incentivised to contribute to additional outcomes will enable DHSC to share the risk of not achieving the Fleming Fund's aims for phase II. The Fund has developed a draft Results Framework for phase II to capture these broader outcomes – this can be seen at Annex N. The project team will commission the Management Agent to outline how they will ensure they contribute to and report on outcomes ahead of renegotiation of the phase 2 contract. DHSC will also ask the Management Agent to develop proposals for activities that support our other priority strategic shifts for phase II.

1.9 The Fund is confident that renegotiating the contract with Mott MacDonald to ensure a continued, and enhanced, focus on outcomes would be in line with the existing contract terms of reference.

1.10 The Fund's preferred option is therefore to extend the existing contract rather than re-procure, with a focus in the negotiation of further risk sharing with the Management Agent on the delivery of outcomes. . The Fleming Fund team have conducted an options assessment available in Figure 3.1 below. The commercial team have committed to working with the Fleming Fund project team to ensure there is a robust negotiation strategy in place for this which considers trade-offs,

the Fund’s best alternative to a negotiated agreement (BATNA)/ walk-away point, and the Fund’s approach to engaging the market.

1.11 If there is not a satisfactory outcome from renegotiation, DHSC has two possible fallback positions:

1.11.1 Extend the contract on existing terms. Ahead of renegotiation, the Fleming Fund project team will commission Mott MacDonald to provide proposals to demonstrate how they will contribute towards outcomes and report on our new Results Framework. The team may subsequently assess that this gives sufficient reassurance that continuing with the existing Management Agent, even without contractual changes, will enable the best possible programme delivery.

1.11.2 Going back out to market. If the project team do not feel assured that the Management Agent will give sufficient focus to our phase 2 priorities, DHSC would re-tender. This would have the added benefit of avoiding the need to re-tender for a phase 3 by ensuring there are adequate extension options through to 2030 (the Fund's ambition for the programme timeline, funding dependent). At this stage, pre-tender market engagement activities would be undertaken to increase interest and build a level playing field in the market.

1.12 The Fleming Fund would need to have concluded renegotiation by June 2022 at the latest to have sufficient time to go back to market ahead of March 2023, when the current contract with Mott Macdonald is due to end. That would allow 8 months for the re-procurement and transition to a new supplier.

1.13 Re-procurement would come with significant risks as outlined in figure 3.1. There would be less time than the procurement timeline for phase I, which took 9 months from pre-qualification bids to best and final offer bids and did not include transition time. However, the Fleming Fund are in a very different position than in phase I – the infrastructure and approach is in place so the project team wouldn't anticipate requiring as complex a procurement process nor a significant

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inception/mobilisation phase as was undertaken previously. Even so, the 8-month period would likely be very challenging in terms of resource for DHSC policy and commercial teams, which are already stretched. In addition, following the timetable set out, the Fleming Fund would be losing out on delivery time as a new contractor came up to speed, as well as risking distracting / disillusioning Mott MacDonald for the final 8 months of their delivery. In this scenario, we may choose to extend the Mott Macdonald contract to enable sufficient time for transition to a new supplier if deemed necessary.

1.14 Re-procurement and delivery by a new Management Agent would also create risks to the Fund's relationships with in-country partners which would need to be carefully managed. The Fleming Fund team would work with grants hub to ensure that grants awarded by Mott MacDonald between April 2022-March 2023 could be handed over to a new Management Agent if required. The Fund will also seek to issue a 'letter of comfort' to the Management Agent to allow them to extend grants beyond March 2023 where needed, in order to prevent the slowing down or ceasing of key grants during 22/23 whilst renegotiation is ongoing. These grants will be awarded on the basis that they will transfer to a new Management Agent if re-negotiations with Mott MacDonald are unsuccessful and if the Fleming Fund team procures a new supplier.

2. Fellowships

2.1 The fellowships scheme is worth roughly 4% of the overall contract. The Fleming Fund is currently undertaking a review to assess their contribution to the overall objectives of the Fund, including sustainability and contribution to AMR data use and policy change. The Fleming Fund team view the overall options to be:

- **Stop the fellowships.** The Fund could stop the fellowship scheme altogether at the end of phase I. However, the independent evaluation of phase I showed that the professional and technical capacity development of in-country staff is key to enabling countries to generate, analyse, share, and use quality AMR data and the fellowship scheme plays a potentially vital role in achieving this. In addition, the specificity and flexibility of the capacity development and mentoring approach, the job training, and fellow's selection process are also considered strengths of the scheme. The Fund's independent evaluator found in 2021 that it is expected that 'the Fellowship Scheme [will] make a vital contribution to building AMR surveillance systems and promoting data use, dovetailing well with Country Grants. The programme is considered key to promoting cross-sectoral networking and collaboration.' For this reason, it is not preferable to end the fellowship scheme, if the Fleming Fund is to leverage the value already gained in phase I and continue to support the enabling environment for strong and sustainable AMR surveillance systems.
- **Continue the fellowships as is**. Whilst there is evidence that the fellowship scheme does play a key part in building the country enabling environment, learning from Itad's evaluations and implementation experience in phase I has brought to light several areas for improvement: (i) The fellowships are focused primarily at the individual level, yet evidence suggests sustainable capacity building requires a broader focus at organisational/institutional level; (ii) Managing Fellows workload and expectations has been challenging, with

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many fellows unable to allocate time to Fellowship Scheme activities; (iii) Lack of formal linkages with ministries and the AMRCC has resulted in limited awareness and engagement with Fellowship Scheme in some contexts, especially where Fellows are not currently members of the AMRCC; (iv) Lack of clarity on the relationships between the Fellowship Scheme, the Country Grants and other FF investments has challenged effective collaboration (although the extent of this challenge varies between countries); (v) Monitoring and evaluation frameworks do not effectively capture outcome level change. For these reasons, the Fleming Fund would not want to continue the scheme as it presently is but seek to make adaptations in response to these learnings.

- **Preferred option: Adapt to ensure sustainability, coherence, and effective monitoring for outcome level change**, incorporating learning from phase I. In consultation with key stakeholders, the team is currently undertaking a review of the scheme to develop and test options. This will include considering partnering with different institutions, possibly by changing supplier via competitive tender or via a grant with one or several academic institutions. The risks and benefits associated with continuing with the current Management Agent or retendering the Fellowship Scheme are listed in Figure 3.2 (following page).

2.2 The Fleming Fund would like to retain flexibility to decide to separate this element and take a different approach, for example putting it out to competitive tender or linking with an academic institution. This decision will be based on the findings from the Fellowships review and Mott MacDonald's proposals for phase II, which the Fleming Fund team expect to have by the end of February.

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3. Value for Money

3.1 The renegotiation strategy will include value for money considerations including where the Fleming Fund could make concessions if needed in exchange for the Fund's asks. The Fleming Fund's 2020 Annual Review recommended a more consistent and evidence-based approach to approving proposed levels for management and overhead costs. This was largely due to Mott MacDonald charging fees in a different way. The Fleming Fund team would like to include this in the renegotiation strategy and seek to agree management and overhead costs with the management agent. This may include:

3.1.1 Overheads – The Fund has worked closely with Mott MacDonald to monitor overheads throughout phase I, through an open book accounting approach. The Fleming Fund would look closely at their overheads planning for phase II, as changes to staffing levels are proposed to meet the Fund's revised requirements.

3.1.2 Profit margins – Mott MacDonald reduced their profit margin to [redacted] for phase I and this has remained static throughout. The Fleming Fund would be open to this increasing for phase II but will set a limit for this within the Fund's negotiation strategy, based on market benchmarks.

3.1.3 Expenses – The Fleming Fund would expect a continuation of the same expenses level as in phase I.

3.1.4 Fee rates – these have been fixed since the initial bid in 2015 so MM may seek to increase this. The Fleming Fund would be open to this increasing for phase II but will set a limit for this within the chosen negotiation strategy, based on market benchmarks.

3.2 The Fleming Fund maintained strong cost controls at all levels of delivery (DHSC, Management Agent and downstream grantee level). In the first five years of the programme, the Fleming Fund have achieved VfM through the Management Agent by:

3.2.1 Rolling out a regional delivery structure through 4 hubs (in Ghana, Uganda, India, Thailand), which ensures more localised support to priority countries and enables grantee monitoring. Regional hubs make savings by reducing the size of the more expensive UK team, ensuring greater regional expertise, and reducing travel costs.

3.2.2 Making procurement savings o[redacted] by centralising the procurement of laboratory equipment on major items through the Management Agent procurement partner, IPA.

3.2.3 Reducing costs passed onto DHSC through use of in-house staff ready to start on day one[redacted] and the use of an existing grant management software system[redacted]

3.2.4 Setting up a process to conduct VfM reviews for every country and grant, with 6 completed to date. Deep dives conducted across grants to provide a range of examples of cost controls and recommendations for strengthening these to ensure VfM is kept on track and lessons can be learned.

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3.2.5 To ensure effectiveness, Mott MacDonald have produced a review of Managing for Effectiveness, which has been assessed by DHSC and the Evaluation Supplier and will lead to the implementation of a series of recommendations. The next review committed to design a basic cost/benefit framework to assess the national AMR surveillance system based on Fleming Fund country experience to date.

3.2.6 Stopping country grants which would not have represented ongoing VfM - the first country grant in Ghana and a country grant in Sri Lanka.

3.2.7 Equity monitored and implemented where possible, including ensuring the fellowships scheme has an equal gender ratio of participants as far as local contexts allow. Cohort 1 fellows comprise 49% women.

3.2.8 Considered VfM in relation to changing demands as the programme has evolved through phase I. Where fees have increased, this has reflected Mott MacDonald's enhanced understanding of the staffing levels and activities required to deliver against objectives or have arisen at the request of DHSC. For example, the addition of a Senior Programme Director, at the request of DHSC, to increase capacity within the leadership team and augment the level of senior leadership to match the increasingly high-profile nature of the Fleming Fund. To make such changes while moderating the impact this has on the overall fees and expenses, many of these increases have been offset through reductions in fees or removal of less vital roles elsewhere in the project.

4. Monitoring, evaluation, and learning (MEL) provider (1% of funding)

4.1 The MEL contract with Itad was procured alongside the MA contract and covers the same period (five years from October 2016, plus an option to extend by a further five years). The Fleming Fund intends to make use of the extension provision within the contract. Itad have performed well through-out the project and are well versed in the Fleming Fund and have an effective evaluation approach in place already. Itad have also developed a very strong working relationship with the current Management Agent and other grantees which has facilitated the smooth running of the evaluation. The evaluation approach has enabled the project team to make adaptive management changes throughout the programme and learn lessons ahead of phase II. The evaluation techniques they use are highly suitable for the programme and enable the Fund's project team to closely measure success. They have also been critical in enabling the Fleming Fund to develop a revised Theory of Change (fig. 1.8) and Results Framework (Annex N) for phase II.

4.2 Retendering would likely take at least 6 months and would require significant resource from the Fleming Fund project team, which is constrained (even more so given the approach proposed for the Management Agent), and Itad are well placed to win again assuming they suggest a similar approach to their current one. A new provider would also need to go through an inception phase to design their evaluation approach, with time and cost implications. The original OJEU notice was for £5.2 million. This contract has also already been extended to March 2023 and including this extension, is valued at £3,684,873.60.

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4.3 There is <£1.5 million remaining in the budget envelope until October 2026. There are certain legal conditions under which this original envelope can be extended. The Fleming Fund team will consult with lawyers to ensure that if the Fund did exceed this, it would meet those legal conditions. Formative deliverables will be managed and reduced for phase II to ensure the Fleming Fund remains within the required budget envelope. The Fleming Fund will also increase onus on the MA to monitor and evaluate themselves, which will support the Fund's wider renegotiation objectives for phase II. See further rationale for this in the management case.

5. New commercial arrangements

5.1 The Fleming Fund may also expand to work in new areas, with new partners, in phase II, in line with the strategic objectives and overall budget set out in this business case. For subsequent procurements not mentioned above, the Fund will continue to follow standard DHSC commercial practices, working with the procurement team and lawyers to seek approval from the Fleming Fund Project Board.

6. Commercial Approach – Grants

6.1 This section outlines our commercial approach to existing grants. The Fleming Fund team will continue to follow standard DHSC grants practices, working with the Grants Hub and lawyers to ensure that all grant awards, extensions, renewals etc., are undertaken appropriately.

6.2 **Developing AMR workforce capacity – CWPAMS, IRC, WHOCC, ODI (and MA fellowships – included in the MA section above) (10% of funding)**

6.2.1 The **Commonwealth Partnership for Anti-Microbial Stewardship (CWPAMS)** grant agreement will be renewed in phase II. CWPAMS builds the capacity of pharmacists with regards to improving anti-microbial stewardship. It commenced in September 2018, originally set to end in June 2020, but has since been extended to June 2022. This grant agreement was awarded on the basis that it provides a specialist and unique set of skills and inhabits a unique space. Whilst a number of other NGOs and corporate delivery partners would be able to deliver stewardship and volunteer initiatives in LMICs, the partnership model twinning UK and LMIC institutions to set up volunteer deployments, skills exchange and on-going virtual partnering is a highly specialist set of skills and was first pioneered by this organisation. It has strong historical relationships developed during more than 30 years of collaboration through the Health Partnerships Scheme with both this grant's countries of interest and across the NHS. It has a unique skillset in delivering a partnerships model with an institution of the complexity of the NHS and in successfully navigating the specific political considerations of working with the NHS. Furthermore, the organisation has consistently demonstrated an ability to deliver the Health Partnerships Scheme effectively and with strong value for money. This is evidenced by consecutive A and A+ scoring in DFID/FCDO annual reviews.

6.2.2 The **UK FAO International Reference Centre for AMR** (IRC) is made up of the following Defra agencies: The Veterinary Medicines Directorate (VMD), the Animal and Plant Health Agency (APHA) and the Centre for Environment, Fisheries and Aquaculture Science (Cefas). The IRC use a peer-to-peer

approach to build workforce capacity and raise awareness of AMR in the animal health, agricultural and environmental sectors. These three organisations are the only ones in the UK to have secured FAO Reference Centre status. FAO's Reference Centre designation is given for organisations that demonstrate key AMR capacities and by showing a track record of active engagement in specific fields of expertise, and FAO counts on Reference Centres to support the Organization's work to combat AMR across sectors in food and agriculture and around the world. No other organisations in the UK are in this position and funding this proposal through a non-competed grant allows DHSC to ensure that it builds on the initial UK government investment from Defra and directly aligns key activities with the Fleming Fund. DHSC consider it highly unlikely that an alternative organisation could leverage the unique networks and skillset required within the given time frame. The Fleming Fund team would therefore plan to renew this grant agreement in phase II.

6.2.3 The Fleming Fund also has a grant agreement for **Overseas Development Institute (ODI) fellowships.** This was a pre-existing scheme funded by DFID/FCO and the Fund agreed to undertake a pilot with ODI for economist fellows focused specifically on AMR. The grant aims to build workforce capacity to support economic policy with regards to AMR. Given their existing scheme, unique positioning, relationships with host governments and expertise in this area, the Fund awarded this grant directly to ODI. The grant agreement runs until 2022 and the Fleming Fund are considering options for renewing this for the remainder of the programme. Should the Fleming Fund deem at the end of the grant that it has been successful and will continue to provide a unique position in fulfilling the strategic objective to build the economic case for AMR, the Fund will renew the grant agreement.

6.2.4 The **WHO Collaborating Centre (WHO CC)** for Reference and Research in AMR and HCAI is part of NIS Laboratories within UKHSA and has supported several global health projects through the International Health Regulations (IHR) strengthening programme, the Fleming Fund Fellowships as a Host Institution, the Fleming Fund EQA Regional Grant for antimicrobial resistance (AMR), and the Antimicrobial Stewardship Development project through the Prosperity Fund. In addition, the WHO CC has strong ties with the UK FAO International Reference Centre for AMR in Animal Health and Agriculture providing a strong One Health partnership.

6.2.5 For Fleming Fund phase II, there is a proposal to use the WHO CC for general support and expertise in working towards building capacity and capability for communicable disease management. This includes elements of advocacy and an advisory role when addressing senior decision makers on strategic aspects of health systems strengthening and healthcare delivery for infections. This partnership will enable DHSC to contribute the UK's expertise to provide technical assistance to partners (the management agent, country grantees, AMR CCs, and consortia) located in LMICs to support capacity development in AMR and AMU with a view to fulfilling the main Fleming Fund objective to harness robust AMR surveillance data.

6.2.6 Given the unique positioning of the WHO CC within UKHSA, including the relationships and experience held with the Fund's key partners including the

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tripartite and the IRC, it would not be appropriate to compete this grant. The Fleming Fund would therefore recommend a direct award to the WHO CC in phase II.

6.3 Mobilising Consensus on AMR – WHO, FAO, OIE, MPTF, South Centre (7% of funding)

6.3.1 **The Tripartite** – made up of the WHO, FAO and OIE – has a global mandate to work on AMR in a way that no other organisation has. They support the Fleming Fund's objectives on building global governance systems, including through the publication of protocols, and through design and implementation of National Action Plans. The WHO has a unique mandate on human health. The FAO is uniquely placed to contribute to the international efforts to address AMR and to provide support to governments, producers, traders, and other stakeholders to adopt measures to minimise the use of antimicrobials and to reduce AMR, while also sensitive to the needs of the food and agriculture sector worldwide. OIE is the intergovernmental organisation responsible for improving animal health and welfare worldwide. MOUs are in place with each of these organisations for AMR-related activity and the Fleming Fund would look to introduce new agreements for phase II recognising the unique position of these organisations to develop global tools and guidance, and to support in-country AMR activity.

6.3.2 The **AMR MPTF** is a Contribution Arrangement under UNDP, who manage this fund via the UN MPTF office in New York. It is a strategic, inter-sectoral, multi-stakeholder initiative to leverage the Tripartite's convening and coordinating power and provides technical expertise to mitigate the risk of AMR. Funding the MPTF allows the Fleming Fund to retain a seat on the Steering Committee and influence the fund's work plan and allocations to country-level requests for proposals. The Fleming Fund would look to continue to provide limited targeted funding to the MPTF in phase II.

6.3.3 The Fleming Fund also supported the **South Centre** through phase I on a non-competed basis and plans to renew this agreement in phase II. The South Centre occupies a unique position with developing countries, as they are an intergovernmental agency specifically designed to support and engage with developing countries, and to promote South-South cooperation. It is a member state led organisation and well respected by developing countries, so is able to shape policy development of developing country governments to a significant extent. It also has significant expertise in the AMR field and offers a specialist function by using its reputation and policy expertise to drive and raise the agenda of combatting AMR. Overall, as a member state led organisation (akin with the UN) but with the sole purpose of supporting LMICs, member states around the world trust and rely on the South Centre perhaps more than many other NGO or commercial supplier.

6.4 Analysing and Using Quality Data – GRAM (6% of funding)

6.4.1 The phase I Fleming Fund grant supported the collection, analysis, and integration of data into the Global Burden of Disease study (the largest global epidemiological tool). The project was led by the Institute of Health Metrics and Evaluation (IHME) and University of Oxford. The Fleming Fund aims to continue this grant to the University of Oxford on a non-competed basis in

phase II to build on the work already achieved. The IHME is the developer and host of the Global Burden of Disease Model and there is no other globally recognised portal of this kind, with the ability to represent geospatial disease modelling capabilities in the same way.

6.4.2 Funding from the Wellcome Trust and Gates will be used for any non-ODA-eligible components of this work – strengthening the VfM proposition.

6.4.3 A further phase of funding will allow critical data gaps to be addressed, and an increased focus on enabling LMICs to use burden data – to support local policy initiatives. For these reasons, it would be inappropriate to compete the grant. It is both more technically and commercially advantageous to continue a non-competed grant with the University of Oxford (as lead grantee).

7. New grants

7.1 The Fleming Fund plans to expand work in new areas in line with the strategic shifts set out in section 6.3 of the Strategic Case. Any new work will align with these strategic shifts and the overall objectives of the programme. The Fleming Fund will review current activity and explore options to work with new partners in some areas. This may result in the Fund stopping some existing activity and establishing new grants and partnerships. Where subsequent grants are awarded not mentioned above, the Fleming Fund team will continue to follow standard DHSC grants practices, working with the Grants Hub and lawyers and seek approval from the Fleming Fund project board.

Financial Case

1.1 Background

1.1.1 **As part of the 2015 Spending Review, HMT awarded DHSC a total of £265m for the Fleming Fund for five years from 2016/17 to 2020/2021.** This budget covered all five original Fleming Fund workstreams which were: 1) surveillance protocols, 2) multilateral grants, 3) country and regional grants, 4) fellowships, and 5) independent evaluation to assess performance of workstreams 3 and 4. Within this, the Business Case expected to spend up to £235m on the Management Agent, which comprised ~£35m for fees and expenses and ~£200m for the grants pot. Given initial delays to country investment, the Fleming Fund used some of this funding for the other workstreams and additional grants were added to respond to strategic priorities (see Fig. 1.2 outlining Fleming Fund phase I investments for reference). The Independent Evaluator's original contract value was for £2.6m. Contract extensions and inception phase costs brought the total contract value to £3.6m. The total maximum value over the 5+5 period was stated as £5.2m in the OJEU advert.

1.1.2 **A budgetary adjustments exercise was undertaken in December 2016 following a drop in GNI.** The Fleming Fund was therefore asked to offer up savings in 2016/17, this came to £51m of budget spread over the period 2017/18 to 2020/21, and it was agreed that this £51m would be returned to the Fleming Fund in 2021/22. HMT and the Chancellor of the Exchequer noted that £51m of ODA funding was sought in 2021/22 to deliver the Fleming Fund, effectively spending over a slower profile. The Fleming Fund was advised to plan on the basis of this funding being available in 2021/22, with the caveat that all funding beyond the Spending Review 21/22 period would be subject to further consideration at the next Spending Review, and therefore couldn't be guaranteed at that stage. On this basis, the Fleming Fund has continued to present itself as a programme of up to £265m.

1.1.3 **However subsequently in March 2021, due to a combination of the impact of COVID-19 and the reduction of ODA spend from 0.7% to 0.5% GDP, the Fleming Fund was allocated £47m for 2021/22 (increased from an initial allocation of £44m) and £42m in 2022/23** from the Investment Committee. This allocation came out of DHSC's total discretionary ODA allocation of £160m in 2021/22 and this decision was based on ODA needs across the Department and steers from Ministers. The 22/23 funding was committed at risk in light of the Spending Review 2020 only being one year, and the Management Agent needing to plan beyond that timeframe. A significant portion of the funding requested at the time - £41.5m and £40m respectively for 2021/22 and 2022/23, was for the extension of the Fleming Fund Management Agent portfolio for an additional 18 months to end March 2023 and to extend the Independent Evaluator (Itad), who are contracted to assess performance of this first phase of the Management Agent's delivery, until March 2023. The remaining funding request was to cover other workstream costs and some phase II scoping costs. The overall planned spend over the life of the project was revised to £245m, which falls within the original 2015 envelope value of £265m.

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1.1.4 **For 2021/22,** the SR20 DHSC ODA settlement as mentioned above was £160m (£61m RDEL and £99m CDEL – of which non-R&D CDEL was £7m). In a break to prior spending review settlements, HMT set a funding envelope for ODA with the discretion left to DHSC to apportion between individual programmes rather than prescribe budgets for each DHSC ODA programme. The Fleming Fund was originally allocated £44m but **following subsequent budget reprofiling across the wider Global Health Security programme, the Fleming Fund was ultimately allocated £47m for 2021/22, of which Mott MacDonald was given a budget of £41.5m.**

1.1.5 **For 2022/23,** as above, in light of the Spending Review 2020 only being one year, and the Management Agent having to slow down activity due to not being able to plan beyond that timeframe, a request was made to the ODA SRO Investment Committee, which the revenue Finance Director chairs, to allow the Global Health Security (GHS) ODA portfolio to future programme at risk. The SRO Investment Committee agreed to the future programming of up to 60% of the existing GHS budget (equivalent to £46m) in years beyond 2021/22. The current commitment, in 2022/23 against this £46m is £43.5m of which the Fleming Fund request makes up £42m.

1.1.6 **The primary purpose of this business case is therefore to seek approval to spend the Fleming Fund's three-year Spending Review 2021 settlement for 22/23, 23/24 and 24/25 in line with the strategic objectives of phase II** (see the Fund's investment pyramid at Fig. 1.3).

1.1.7 Given the precedent set out in the arrangement agreed at 1.1.5, and in preparation for the same eventuality at the end of the 22-25 SR period, this Business Case also **seeks approval from the Investment Committee to support pre-commitment of up to £40m in year 4 (25/26) at risk**, but with a break clause included at the end of year 3 to ensure DHSC can exit at that point if necessary. **Approval from Investment Committee to spend funds committed at risk in year 4 will be sought in year 3.** A 4-year contract will allow the Management Agent to plan for the outer years and prevent the slowing down or closure of activities which are essential for achievement of the Fleming Fund objectives.

1.1.8 The Fleming Fund already has some contractual commitments in place which extend beyond phase I, and FY21/22, which are critical to the ongoing delivery of the programme, namely the Management Agent contract and the contract with the Independent Evaluator. There are also other arrangements in place, such as costed extensions and no cost grant extensions, to help manage the transition from phase I to phase II. Approvals for the necessary extensions, costed or otherwise, have been (or will be) sought outside of the business case approvals process (where more immediate decisions are required i.e., before March 2022). This information is detailed in Annex G but is also summarised here to provide assurance that the Fleming Fund is managing the transition between the two phases of the programme to avoid gaps in delivery and/or the loss of key delivery partners and relationships. See Management Case, for detail on how the Fleming Fund will manage where there may be concurrent delivery of phase I and phase II activity from April 2022 onwards.

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1.1.9 Contractual commitments which will draw on phase II funding from April 2022 onwards:

- **Management Agent (Mott MacDonald)** – In March 2021, DHSC's Investment Committee approved an extension in contract variation 13 to March 2023 to the value of £40m.
- **Independent Evaluation Supplier (Itad)** – The contract has been extended to March 2023 in contract variation 10 (approved by DHSC's Investment Committee in March 2021), to evaluate the Management Agent's implementation. The extension commitment is up to the value of £684,765 for FY22/23.

1.1.10 Grant commitments which will draw on phase II funding from April 2022 onwards:

- **Overseas Development Institute** – In 2018 ministers approved £1.5m budget over 5 years to run a cohort of Economic Fellowships as part of the Fleming Fund. The original grant agreement ends in March 2023 and the remaining budget is £851,000 for FY22/23, though as the Fleming Fund team designs phase II activity, allocated budget and associated forecasting is likely to vary.
- **Global Research on Antimicrobial Resistance Project (GRAM)** – Current grant addendum runs until March 2022; the Fund now seeks a costed extension of £500k to run until July 2022 to enable a transition phase/consolidation of phase I achievements. £250k of the costed extension will draw upon FY22/23 budget.

1.1.11 Grant commitments which will draw on phase I funding spent or accrued by end of March 2022 (included here as payments made in advance but some activity will take place in phase II timeframe):

- **Commonwealth Partnerships for Antimicrobial Stewardship Programme (CwPAMS)** – Grant addendum approved additional funding of £500,000 to support delivery during a transition phase from July 2021 to June 2022. This has been factored into phase I spend.
- **Grants to the Tripartite (FAO, OIE, WHO)** – In the case of possible underspend in FY21/22, costed extensions will be sought. Payment will be made in advance using phase I funding before the end of FY21/22, though activity is likely to run into phase II from April 2022 onwards. New grant agreements for phase II will be made when phase I agreements expire.

1.2 Financial Context for SR2021

1.2.1 The Fleming Fund is funded through Official Development Assistance (ODA), often referred to as overseas aid or UK aid. ODA is the internationally agreed criteria governed by the OECD Development Assistance Committee for funds provided to developing countries or multilateral institutions to fight poverty and promote development. The OECD DAC defines a list of countries which are eligible to receive ODA. This list is revised every three years and changes depending on per capita income of a country.

1.2.2 The 2002 International Development Act committed the Government to spend UK aid for the primary purpose of reducing poverty. Whilst developing

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countries must be the primary beneficiary, the UK and other non-ODA eligible countries can also benefit, but as a secondary outcome. The 2015 International Development Act enshrined in law a commitment for the UK Government to spend 0.7% GNI on UK aid. This commitment was paused in 2020, and a revised temporary 0.5% GNI commitment was agreed, due to the economic uncertainty during the COVID-19 pandemic. The UK reports all UK aid spend to OCED DAC on a bi-annual basis via FCDO.

1.2.3 The effectiveness of UK aid spending is scrutinized in several ways. In 2010 the government established the Independent Commission for Aid Impact (ICAI) which has a remit to review and scrutinise UK aid funded activities across government. DHSC has been involved in several recent reviews including reviewing 0.7% UK aid spend target. The Foreign Secretary is responsible for ensuring that an annual independent evaluation of Value for Money (VfM) is carried out. In addition, HM Treasury and FCDO co-chair a working group, reporting to Ministers, to ensure VfM.

1.2.4 The Fund is subject to all the government's transparency objectives in relation to aid and subject aid to robust independent scrutiny through the Cabinet Office Grants Standards.

1.3 ODA Eligibility of the Project

1.3.1 The primary purpose of all GHS' ODA funded activities is to address global health threats which disproportionally affect developing countries. Lord O'Neil's Review of AMR found that AMR was likely to disproportionately affect low and middle-income countries (LMICs). The Fleming Fund invests in interventions, such as improving laboratory capacity and diagnosis, as well as data and surveillance of AMR, to enable LMICs to monitor and address the effects of AMR (see section 4 of the Strategic Case for more detail). Where grants, research, or online learning is developed by an international delivery partner, this will be for the direct benefit of ODA eligible countries. As an additional assurance measure, quarterly reports will include confirmation of the ODA-eligibility of activities. All Fleming Fund Country and Regional Grants and Fellowships (including all investment types) will be for disbursement in ODA eligible countries as per the OECD DAC list[35]. Annex E contains details of the Fleming Fund's approach to country selection.

1.4 Financial Monitoring between DHSC and HMT

1.4.1 ODA is measured on a calendar year basis. To ensure the UK Government meets its commitment of spending 0.7 percent GNI on ODA, reduced to 0.5 percent GNI in 2022[36], DHSC has been tasked with spending at least 80 percent of its ODA ring-fenced financial year budget before 31st December each year.

[35] OECD DAC List of ODA Recipients (2021)
[36] International Development (Official Assistance Target) Act 2015

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1.4.2 The Fleming Fund project team will provide robust financial forecasts to financial colleagues to enable DHSC to meet HMT and FCDO ODA reporting requirements as well as internal DHSC Group financial reporting.

1.4.3 The Fleming Fund will adhere to any relevant terms outlined in the Department's 2021 Spending Review Settlement Letter when it is received.

2.1 Budget 2022-26

2.1.1 In the 2021 Spending Review, DHSC was allocated £832m of ODA funding spread across all ODA programmes. The Global Health Security (GHS) programme has been allocated £357m over the three-year period. Within this, **the Fleming Fund has been allocated an indicative budget of £193.5m ODA over the next three years from 2022/2023 through to 2024/2025, with the potential for funding to increase depending on wider pressures in the GHS portfolio. The Fleming Fund is therefore seeking approval to commit up to a maximum £210m in 22/23 to 23/25, subject to that wider ODA funding being available within the GHS budget.**

2.1.2 This Business Case **also seeks approval of a commitment at risk of £40m in 2025/26** to allow the Management Agent to plan for longer-term delivery of key components of the fund and prevent early closure of core project activities in the case of a late SR settlement in 2024. **Approval to spend the funds committed at risk in year 4 will be sought from the Investment Committee in year 3 and a break clause embedded into the contract to allow exit at end of year 3 if this approval isn't secured.** Without budget cover beyond March 25, the downstream country and regional grants would stall from March 2024, with no new grants being feasible beyond this date. Agreeing a four-year contract with the MA now will also ensure that this fourth year is part of the planned current commercial negotiations with the MA as set out in the commercial case. If the Fleming Fund agrees a subsequent fourth year at a later date DHSC will have less leverage in these negotiations, especially as the MA knows the subsequent phase will be re-tendered. This is outlined in further detail at point 2.5. Sufficient provisions including a clear break clause at the end of year 3 will be embedded into the contract to minimize risk exposure and allow early exit of commitments, which will also apply to downstream grants, if funding is not secured in future Spending Review. **Therefore, the Fleming Fund is seeking approval to commit at risk up to a maximum of £250m of ODA over four years. This includes a maximum of £210m over 22/23 - 24/25, with hard approval sought for £193.5m and provisional approval for the remaining £16.5m** as long as this remains affordable within the overall threshold approved for GHS to pre-commit funding in outer-years**.**

2.1.3 Whilst specific budgets have not yet been confirmed with partners/grantees, the Fleming Fund project team sought phase II proposals based on different funding scenarios from partners, and has drawn on this to inform the proposed budget allocation, which is aligned to the strategic objectives of phase II. The £193.5m indicative budget (£172.5m RDEL and £21m CDEL) for the Fleming Fund from the UK's ODA budget will be allocated to five investment areas. This would also apply to outer year spending. This is

detailed in the investment pyramid in the Strategic Case (see Figure 1.2) and is in line with the preferred option in the Economic Case:

Figure 4.1. Fleming Fund estimated investment areas

	Proposed investment split in phase II	Change from investment split in phase I
Strengthening national surveillance programmes	76-79%	Combined workforce and systems: up from 80%
Developing AMR workforce capacity	9-10%	
Mobilising consensus on AMR	5-7%	Down from 14%
Analysing and using quality data	6%	Up from 5%
Monitoring, evaluation, and learning	1%	Consistent

2.1.4 The funding apportioned to these investment areas reflects the new strategic shifts for phase II and responds to lessons from the first phase and the changing global context. Over the course of the three-year Spending Review period and in outer years, the Fleming Fund propose increasing funding and focus on strengthening national surveillance systems to support the use of quality data, by deepening the Fund's activities in-country, in areas such as making the economic case for tackling AMR, regional animal health and environmental activity, and targeted activity on substandard and falsified medicines. Alongside this, the project team proposes to decrease the proportion of funding for mobilising consensus on AMR. As such, the Fleming Fund's funding allocations reflect the programme's strategic ambitions for phase II, building on phase I investments and responding to the changing context since the start of the Fleming Fund, and this translates into the spend profile outlined below. It is likely that the exact split between investment areas will vary somewhat from what is set out in Figure 4.1, over the course of phase II delivery to enable the programme to effectively manage any underspends or emerging priorities over the period.

2.2 Spend Profile

2.2.1 The proposed spend profile for the £193.5 million budget is outlined in Figure 4.1 below (outer year profiles are provided at 2.5):

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Figure 4.2. Spend Profile 2022-25

Headline figures (in £m)	22/23 **(£61m)**	23/24 **(£62.5m)**	24/25 **(£70m)**	25/26 **(£40m[37])**
RDEL				
1. Strengthening national surveillance – 76%-79%	41.04	43.85	48.51	30.00
2. Developing AMR workforce capacity – 9-10%	5.40	4.99	6.30	1.80
3. Mobilising consensus on AMR – 5-7%	3.78	2.78	3.78	1.00
4. Analysing and using quality data – 6%	3.24	3.33	3.78	1.80
5. Monitoring, evaluation, and learning – 1%	0.54	0.55	0.63	0.40
RDEL Total	54.00	55.50	63.00	35.00
CDEL	7.00	7.00	7.00	5.00

2.2.2 The annual budget profile for the Fleming Fund set out in Figure 4.1 is indicative in order to retain the flexibility to adjust the allocation across the different Fleming Fund and Global Health Security (GHS) projects. Whilst the Fund's project team has indicated the planned spend, learnings to date and annual underspends have shown the need to over-programme by around 20% each year to achieve this. This means the Fund's commitment levels each year will exceed the indicative annual budget by around 20%, and where additional funding is available in the wider GHS programme, the Fleming Fund may exceed the annual spend profile.

2.2.3 The Fleming Fund has options available to ensure the overall GHS programme remains affordable within its annual ODA budgets. Over-programming is a necessity to offset the likely underspend, but will be managed closely to ensure that the annual GHS budget is not exceeded. Close financial management will provide early indications of whether the Fund is likely to spend at the over-programmed level and can draw on underspends across GHS. If required, the Fleming Fund project team can slow down or pause programme activity, push out or reprofile payments, or manage pressure through reducing spend elsewhere in the programme to ensure that there is no overspend across GHS annual budgets. There is similar flexibility

[37] Beyond March 2025, forecasted programme costs have been reduced in recognition that there is no SR confirmed for this period and the Fleming Fund will only have provision to future programme up to 60% of the existing GHS ODA budget as agreed by the SRO Investment Committee. As such these figures do not align with the investment areas split set out in the left-hand column. As referenced elsewhere in the case firm approval to spend the funds committed in year 4 will be sought from the Investment Committee in year 3 and a break clause embedded to allow exit at end of year 3 if this approval isn't secured.

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in other GHS projects. The Fleming Fund will avoid a position where the department is at risk of incurring exit costs or sunk costs as a result of such over-commitment, continually refining the project team's approach based on trends and experiences from previous years.

2.2.4 As such, the Fleming Fund is **seeking Investment Committee approval to spend the indicative budget of £193.5m as well as approval to increase this budget up to £210m if required, and as long as this remains affordable within the overall GHS ODA three-year Spending Review allocation.** The Fleming Fund team commits to update the Investment Committee if the budget over year 1-3 is increased beyond £193.5m.

2.3 Proposed Programming for Phase II

2.3.1 As outlined above, funding will be allocated towards programming in the five investment priority areas:

- Strengthening national surveillance systems – approximately 76-79% of total funding. This includes the portfolio of country grants, regional grants and strategic alignment grants implemented by the Management Agent, as well as the Management Agent's fees and expenses. This priority area will also use the majority of CDEL funding to support building laboratory capacity.

- Developing AMR workforce capacity – approximately 9-10% of total funding. This could include the delivery of the Fellowships Schemes (delivered by the Management Agent and by ODI), as well as a number of other grants, such as for the Commonwealth Partnerships for Antimicrobial Stewardship (CwPAMS) Programme.

- Mobilising consensus on AMR – approximately 5-7% of total funding. This could include funding for grants to the Tripartite (WHO, FAO, OIE) and a small amount of funding for meetings, engagement, and communications.

- Analysing and using quality data – approximately 6% of total funding, for grants such as the Global Research on Antimicrobial Resistance Project (GRAM) and the Fund's grant to WHO for work on substandard and falsified medicines, but could also include funding for other grants that may support this priority area.

- Monitoring, evaluating, and learning – approximately 1% of funding, which is allocated to the Fund's Independent Evaluators who assess the relevance, efficiency, effectiveness, impact, sustainability, and coherence of the Management Agent's results and delivery.

2.3.2 Detail on how budget lines allocated to the Fleming Fund's five investment priority areas might fund different grants, projects and suppliers can be found in Annex O.

2.3.3 The CDEL budget is predominantly allocated within the national surveillance line, however there may be some other areas that require CDEL spend, for example within the workforce capacity line. This will be a very limited amount and will be identified through more detailed forecasting with partners/grantees.

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2.3.4 Pending business case approval, the Fleming Fund will provide indicative budget allocations to the Management Agent and other partners/grantees within the agreed budget envelope. Partners will then provide detailed forecasts for activity in line with the Fund's strategic objectives. The sequence of grant disbursements can be managed in order to meet annual targets.

2.3.5 To note, where it makes sense to do so throughout the lifetime of the Spending Review period, percentages splits for the investment priorities may shift slightly but allocations will remain affordable within the annual GHS budget, and the overall three-year Spending Review allocation for GHS.

2.4 RDEL/CDEL Split

2.4.1 The Fleming Fund has been allocated both RDEL (resource) and CDEL (capital) budget as achieving the programme's objectives will require investment in equipment and infrastructure as well as resource. Figure 4.3 below sets out the SR21 budget allocations for the Fleming Fund.

Figure 4.3. RDEL/CDEL Split

	RDEL	CDEL
2022/2023	£54m	£7m
2023/2024	£55.5m	£7m
2024/2025	£56m	£7m
2025/2026	£35m	£5m

2.4.2 The splits indicated in Figure 4.3 are indicative budget envelopes and precise requirements will be informed through regular forecasting from the Management Agent. The Fleming Fund project team will provide updated forecasts for reporting requirements as the grants are determined ahead of phase II and as this information is received from the Management Agent.

2.5 Outer Years of Fleming Fund – Beyond SR21

2.5.1 Beyond the current Spending Review period 2022-25 and on the basis that the Fleming Fund's re-negotiation with Mott MacDonald is successful, as per the project team's preferred option in the commercial case, the 5+5-year contract with the Management Agent would run up to March 2026, with scope to further extend until October 2026 at the very latest whilst the re-tender process is concluded. Beyond March 2025, forecasted programme costs have been reduced in recognition that there is no SR confirmed for this period and the Fleming Fund will only have provision to future programme up to 60% of the existing GHS ODA budget as agreed by the SRO Investment Committee (see Figure 4.3 below for estimated figures). The Fleming Fund would have to go out to tender again for the Management Agent contract for delivery beyond this timeframe and so ahead of this (and as part of preparations for the next Spending Review), the project team will re-assess the longer-term continuation and spending projections for the Fleming Fund (see Commercial Case for more information).

2.5.2 In order to prevent unnecessary slowing down or closure of key activities, due to uncertainty of funding and commitment from DHSC, this Business Case

seeks approval from the Investment Committee to commit to programming funding for 25/26, subject to the associated funding being secured in SR24. This pre-commitment at risk would be in line with the approval previously given by the ODA SRO Investment Committee for GHS to commit a proportion (50-60%) of its current ODA budget into future years in lieu of funding being confirmed. This flexibility is required due to the exceptional nature of ODA programmes where longer-term investments are needed to secure sustainable development results and protect Value for Money. For Fleming Fund specifically, it reflects the length of time required to embed new surveillance systems in LMICs and the need to provide assurance to our Management Agent, Independent Evaluator, and relevant partners to allow for planning into 25/26, to either continue the programme beyond this SR period, or to allow for sustainable closure and handover of activities.

2.5.3 As such, the Fleming Fund is **seeking Investment Committee approval to** enter into contractual commitments of up to £40m in year 4 (**25/26), as long as this remains affordable within overall threshold approved for GHS to pre-commit funding at risk in outer years.** The Fleming Fund will revert to the IC in year 3 for approval to spend the funds committed at risk in year 4. Overall financial risk to DHSC will be mitigated via a break clause in contracts and our ability to exit both the MA contract and all downstream grant agreements at our sole discretion, with 3-months' notice. We can also set annual budget caps in the MA contract which will ensure outer year commitments do not exceed that threshold.

Figure 4.3. Projected Spend in Outer Years (FY25/26 onwards)

Headline figures (in £m)	22/23 **(£61m)**	23/24 **(£62.5m)**	24/25 **(£70m)**	25/26 (£40m)	26/27 (for info only)
RDEL					
Strengthening national surveillance	41.04	43.85	48.51	30.00	30.00
AMR workforce capacity	5.40	4.99	6.30	1.80	1.80
Analysing and using quality data	3.24	3.33	3.78	1.80	1.80
Mobilising consensus on AMR	3.78	2.78	3.78	1.00	1.00
Monitoring, evaluation, and learning	0.54	0.55	0.63	0.40	0.40
RDEL Total	54.00	55.50	63.00	35.00	35.00
CDEL	7.00	7.00	7.00	5.00	5.00

2.6 Accounting Treatment

2.6.1 The Fleming Fund comprises both RDEL (resource) and CDEL (capital) budget; RDEL can be spent on frontline and resource costs for things like

salaries, rent and bills (nonphysical things), and CDEL can be spent on infrastructure and equipment costs for things like laboratory kit (physical things). The Fleming Fund's threshold for capitalization and the classification of assets is anything with a value of £500 ODA or more (full definition is covered below in 2.6.2); this differs from the standard DHSC domestic classification of £5,000 but is in line with FCDO's Programme Operating Framework guidance. The lower threshold has been adopted due to the higher risk of fraud within international aid delivery programmes and the need to manage this risk very carefully.

2.6.2 Any equipment and supplies purchased from programme funds are defined as capital assets if they meet both of the following criteria:

- They have a useful life of more than one year; and
- The purchase price or development cost of the asset is in excess of £500 or equivalent in local currency. The value might be for a group of assets rather than each individual asset when it comes to what are known as "attractive" assets such as mobile phones, laptops, satellite phones etc.

2.6.3 In phase I Mott MacDonald expenditure was the only element of the Fleming Fund budget where the agreement and comprising grants allowed for capital spend; as such Mott MacDonald are required to keep a register of fixed assets in line with the classifications above, including all land and buildings acquired or improved within the contract. If other grants are allocated CDEL in phase II (though it would be a very small amount as stated in 2.3.3), they will also be required to complete the relevant asset registers (see section 5 on Financial Controls below for more information on asset management).

2.7 VAT Status of Fleming Fund

2.7.1 In line with phase I and as confirmed with DHSC's Head of VAT and Tax, the Fleming Fund is generally VAT reclaimable, and any VAT charge is reclaimed upfront. This applies to a couple of budget lines, for example for the Management Agent fees and expenses, but the majority of the Fund's spend is on grant payments, which are VAT exempt. As such, VAT is excluded from budget figures, and where there are VAT implications these have been highlighted in Annex O.

2.8 Management Agent Costs

2.8.1 The Management Agent (MA) costs for implementation from 10th October 2016 until the end of March 2023 (when the current contract expires) are currently forecast to [redacted] they include:

- Staff fees (presented in day rates) – this includes profit margins, overheads, and technical assistance
- Expenses (much of this is travel)

2.8.2 MA costs overall are capped while also being driven in part by achievement of KPIs and SLAs (See Annex P).

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2.8.3 All of the MA's costs are subject to UK VAT which will be invoiced in addition, however, to note, VAT costs have been excluded from the Fund's budget allocations because they are reclaimable (VAT costs on management fees are paid centrally then reclaimed by DHSC).

2.8.4 The MA is required to manage the risk of exchange rate fluctuations within their fixed day rates as DHSC will not increase rates to accommodate such fluctuations. Large suppliers who are accustomed to working on multinational grant management projects will be used to absorbing this risk themselves and will account for this in their proposed rates. This is captured contractually.

2.8.5 The MA fees and expenses for April 2022 onwards is currently assumed to be per financial year, however this is based on phase I spend and is subject to change. Mott MacDonald reduced their profit margin to for phase 1 and this has remained static throughout. Fees and profit margins may increase in phase II, depending on the renegotiation of the contract. As outlined in section 3 of the Commercial Case, the Fleming Fund would be open to this but will set a limit for this increase within the project team's negotiation strategy, based on market benchmarks. the Fleming Fund is confident a slight increase in Management Agent fees and expenses for phase II are both manageable within the budget envelope for the programme.

2.8.6 Further information on the above, the renegotiation process and the project team's approach to agreeing Management and overhead costs with the MA is contained within the Commercial Case.

2.9 Evaluation Supplier Costs

2.9.1 DHSC has contracted the Independent Evaluator Itad at a total cost of £3,684,873.60 to date to run alongside the Management Agent contract. The original contract value was £2.6m for the evaluation of the country and regional grants and fellowships however the original OJEU notice was for £5.2 million under a 5 + 5-year contract extension option (which is the same as for the Management Agent). This contract has been extended to March 2023 and includes additional deliverables bringing the total current contract value to £3,684,873.60, leaving <£1.5 million in the budget envelope until October 2026. The Fleming Fund intends to use the +5-year extension option for phase II and will look to manage the scope of evaluation down to stay within the budget envelope and focus more on assessing achievement of outcomes, impacts and value for money as outlined in the Management Case. There is however the possibility of extending the contract value by a further 50% up to a ceiling of £7.8m if needed. The aim of the evaluation was to assess the relevance, efficiency, effectiveness, impact, sustainability and coherence of Management Agent results and delivery. The final summative evaluation will be received latest December 2022 to inform phase II design.

2.9.2 Itad have always performed to a high standard and there is potential for continued efficiency savings as part of a new contract. Itad's proposed personnel fee rates were challenged and reduced under a variation to their contract in August 2018 (receiving Ministerial sign off); they have been fixed for three years and for the current contract duration to March 2023. To challenge these rates, the fees were benchmarked against rates for similar

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evaluations undertaken for the FCDO at the point of tendering, and a fee rate band was agreed for key roles. The fee rates were reduced across the entire evaluation team, [redacted], and with the rate banding system removed with rates now set against team roles. This represents greater Value for Money for this contract and increases DHSC's capacity to challenge any future rate increases. Under this variation it was also agreed that all travel expenses will conform to DHSC's travel requirements.

2.10 Proportion of Spend on Programme vs Admin Costs

2.10.1 There has been extensive analysis conducted on the level of administration costs associated with the Fund's grants as part of the Annual Review process. Key findings include:

2.10.2 Extract from Annual Review 2019: There is good evidence that costs are being actively managed at the mobilisation stage, through the grant review/ award process. Management and Overhead costs (M&OH)[38] and Indirect Costs (IDC)[39] are closely monitored.

2.10.3 In addition, quarterly reporting is in place with all grantees, which includes review and discussion on budget and actual variances. Where activities are not completed as planned, discussions are held between regional teams and implementing partners to reschedule activities.

2.10.4 The Management Agent has used grantee data to implement a broad target on grantee management, overhead and indirect costs, to ensure the country grants and regional grants don't routinely exceed [redacted] of the grant value at the point of award. The Fleming Fund will review this approach as part of phase II design.

2.10.5 The Commercial Case considers how drawing on this analysis can support the renegotiation of grants/contracts with a view to improving the overall admin/programme ratio.

3. Financial Monitoring between DHSC, MA and Grantees

3.1 Management Agent

3.1.1 The Management Agent is required to provide the following to support DHSC in its financial monitoring and management:

- Quarterly review meetings including a review of quarterly grantee progress and reports, the previous quarter's actual spend and forecasts for the following quarter. Downstream grantees are required to provide itemized invoices, copies of receipts etc. alongside quarterly financial and activity reports, which are collated and analysed by Mott MacDonald to provide

[38] M&OH costs are attributable to a project but not to specific activities detailed in the workplan. These are typically project finance and admin staff, project office costs, etc.
[39] IDC, or Non-Project Attributable costs (NPAC), are the costs incurred that cannot be directly attributed to a specific project. These include the running costs of the organisation (HR and finance functions, Head Office, and governance costs).

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management information and to report quarterly to DHSC on progress and challenges (see Management Case for detail on downstream grantee monitoring, reporting and performance management).

- Monthly financial reports and meetings, indicating what disbursements have been made, any reprofiling of spend and the planned spend for the remaining duration of grants. Mott MacDonald provide monthly forecasts to DHSC based on forecasts submitted by downstream delivery partners. Where there are concerns with forecasting, they work closely with partners to address them. Forecasted spend is RAG rated against an agreed set of criteria to indicate confidence in both timing of payment and amount, and discounting of forecasts can be applied provided there is a rationale.
- Annual audited financial statements
- Annual forecasts submitted with the annual report
- See section 5.2 for detail on financial controls, measures taken to prevent risk of loss or misuse of funds and asset management.

3.1.2 These are formal mechanisms through which the Fleming Fund ensures the Management Agent is on track to meet annual financial targets and ODA reporting requirements. The process/mechanism by which funds are disbursed to the Management Agent will be the same as for phase I and this is outlined in section 4.1-4.4 below.

3.1.3 During phase I, DHSC saw an improvement to the Management Agent's financial management overall. This was in part because in 21/22 the Management Agent was asked to over-programme by [redacted] to mitigate against underspend. They also share monthly reports and attend monthly meetings to discuss and review the latest financial spend and forecast figures; as part of this reporting cycle, they provide RAG ratings on the timing and amount of all forecasts which are used to inform DHSC's confidence assessment and resultant risk adjusted forecasts. This helps DHSC to manage the risk of under/over-spend. This has improved the reliability of forecasts and so will be retained in phase I, however underspend does remain a factor.

3.1.4 In phase II, pending renegotiation of the Management Agent contract, the project team will work to further combat optimism bias in forecasts and ask MM to raise their over-programming to [redacted], as indicated in section 2.2.2-3. The Fleming Fund will also request that the Management Agent creates a more rigorous process for holding their grantees to account on providing reliable forecasts and invoices for spend e.g., a hard deadline should be set at the end of each financial year for grantees to raise invoices to reduce variance and uncertainty around accruals.

3.1.5 For the remainder of the Fleming Fund portfolio, the project team may also encourage a small amount of over-programming. Encouraging delivery partners to plan some additional project activity, knowing there will be some slippage and optimism bias, is an important way of ensuring that the Fleming Fund delivers against the overall budget and helps to mitigate against the risk of underspend due to project delays or cancellation. This approach also provides DHSC with choices during implementation as to where to prioritise investment, which will be an important part of maximising VfM and impact.

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3.2 All Other Grants

3.2.1 Proportional to the size of the grant and as agreed with the DHSC grant lead, each grant recipient provides detailed project financial reports on a quarterly/6-monthly/annual basis that set out the actual expenditure of the previous disbursement against the approved funded activities budget and quarterly/6-monthly/annual forecast expenditure for DHSC's financial year (1st April-31st March) in relation to the funded activities.

3.2.2 These financial reports are reviewed by DHSC alongside progress reports and take into account delivery of funded activities during the funding period against KPIs and/or agreed outputs to ensure the aims and objectives of the funded activity are met and that the terms and conditions of the grant agreement are being adhered to.

3.2.3 The grant recipients should provide revised forecasts of income and expenditure:

- When these forecasts increase or decrease by more than [redacted] of the original expenditure forecasts; and/or
- Alongside quarterly/6-monthly/annual finance reports; and/or
- At the request of DHSC.
- Each grant recipient is requested to keep separate, accurate and up-to-date accounts and records of the receipt and expenditure of the grant received from DHSC and any possible income generated from the funded activities.

3.2.4 DHSC can request audits of delivery and/or performance of the funded activity or request access to audited accounts if required.

3.2.5 After the end of DHSC's financial year (31st March) for any year (1st April – 31st March) in which they receive grant funding, grantees must provide:

- Unaudited statement of income and expenditure by 30th April;
- Signed declaration from grant recipient's Finance Director or equivalent that all expenditure was in line with eligible expenditure schedule;
- Grant report which sets out activity achieved against the project's aims in line with the agreed reporting schedule.

3.2.6 Where the grant agreement runs for a term longer than one financial year, the grant recipient must provide the following details to DHSC before the end of each financial year:

- Schedule of the funded activities and estimates of income and expenditure for the next financial year, together with forecast outturns for the current year;
- Statement setting out the total grant agreed for the year;
- Details of any additional funding for delivery of the funded activities, other than the grant, with full details of how it is to be spent;
- Level of balances held by the grantee at the end of the financial year.

3.2.7 Each grant should also be reviewed annually taking into account the relevant documentation above (as agreed with the DHSC grant lead and proportional to the size of the grant), with a view to assessing the grant recipient's delivery of the funded activities against the annual KPIs and/or agreed outputs. Annual reviews may result in the continuation of existing plans, changing the size of

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the grant for the subsequent financial year, re-defining the KPIs, termination of the agreement and/or recovery of unspent/surplus grant.

4. Financial Disbursements

4.1 This section aims to outline the various mechanisms the Fleming Fund uses to disperse payments to grantees and suppliers. The majority of costs are through the Fund's Management Agent, and so the mechanisms are outlined in more detail for Mott MacDonald.

4.2 Contracts: Management Agent Fees and Expenses

4.2.1 The Management Agent fees, and expenses (including the provision of technical assistance budget) are paid monthly in arrears on an actuals basis. Each month ██████f the requested actuals will be retained against deliverables measured quarterly and KPIs measured annually. This approach mitigates the risk of loss or misuse of HMG funds, incentivises performance, and drives the project's VfM (see Management Case for more detail).

4.3 Contracts: Management Agent Grant Disbursements

4.3.1 Grant funds disbursed to grantees in low- and middle-income countries and other activities such as fellowships and operational research that are counted as grants are not subject to UK VAT. This will be reflected in invoices to DHSC.

4.3.2 Due diligence will be completed on all potential grantees ahead of any grant agreement being signed or grant disbursement to grantees to ensure appropriate financial risk management. As detailed in the Management Case, no grant funding will be made without DHSC's approval. Full details on the financial appraisal process can be found in Annex Q and the technical appraisal process in Annex R.

4.3.3 Financial disbursements to downstream grantees will continue to be made by the Management Agent to the relevant international or country bank accounts from the UK. Disbursements are made based on quarterly claims primarily in arrears against the agreed workplan and budget in the grant agreement between the supplier and grantee. Workplans and budgets are structured in line with the outputs identified in the terms of reference for each grant, with quarterly reporting against both for performance monitoring and payment. Performance reporting is consolidated into a quarterly monitoring data report for DHSC to summarise progress across the grants programme.

4.3.4 As above, wherever possible, payment is made in arrears upon confirmation of delivery and following checks on expenditure by the MM team. However, some grantees in low resource country settings may not be able to scale up project activities without some level of up-front funding, to procure equipment or hire staff for example. In these cases, the Management Agent will be required to make an up-front payment to the grantee, restricted to one or two quarters in advance wherever possible, with future payments only payable

against expenditure statements. In all other respects, the routine reporting in paragraph 4.3.3 will apply.

4.3.5 Given the number of grants and scale of funding for the grants programme, DHSC provides just-in-time payments to the Management Agent (only for grants) so that funds can be disbursed to downstream grantees in a timely manner. This approach is a routine arrangement between FCDO and their suppliers and can be achieved through a HMT pre-financing mechanism that was arranged with DHSC in December 2016. The Management Agent has a dedicated client bank account for the Fleming Fund where ring-fenced funds can be held ahead of being disbursed to grantees. In order for funds to be released, the Management Agent provides a summary of grant payments due each quarter for DHSC's review and approval, prior to funds being released into the client bank account. This ensures DHSC always retains sight of all payments, including advance payments made to grantees through this mechanism.

4.4 Contracts: Management Agent Country Grants with DHSC Disbursal

4.4.1 UN agencies are the grantee for a small number of Country Grants where they have been deemed the most suitable organisation to manage the grant. As UN agencies are unable to sign agreements with private commercial organisations, the grant agreements for these grants are held directly between DHSC and the relevant downstream grantees. For these grants, the Management Agent will continue to maintain oversight, but funding is disbursed directly to the UN agency grantee by DHSC (rather than being facilitated by the Management Agent). Advance payment for UN agencies can be up to six months in advance, with future payments only payable against expenditure statements. In all other respects, the routine reporting in paragraph 4.3.3 will apply.

4.5 Contracts: Itad and Softwire

4.5.1 The Fleming Fund also holds contracts with Itad and Softwire for Independent Evaluation and technical support with the Fleming Fund website respectively. All such invoices are paid in arrears and only submitted to be paid once they have been reviewed against the relevant forecasts and quarterly reporting documentation, and any necessary spot checks have been completed.

4.6 Grants: Fleming Fund Portfolio

4.6.1 The grants outside of the Mott MacDonald portfolio are predominantly paid in advance in line with the payment schedule outlined in individual grant agreements (or in a Memorandum of Understanding as DHSC has with the UK FAO International Reference Centre for AMR). These are un-competed grants where the grantee organisation is uniquely positioned to help DHSC deliver the Fleming Fund's strategic objectives.

4.6.2 Disbursement dates are agreed within payment schedules, however grantees must prove they have delivered the agreed activity to date, that they have committed or spent ███ of the previous disbursement and that they require

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the next tranche, before payment is released. The DHSC lead for each grant will also ensure that activity and expenditure is discussed in regular meetings and reporting, and will only process the next disbursement once checks have been completed and confirmation on the above has been received from the grantee.

5.1 Financial Controls & Risk of Loss or Misuse of HMG Funds

5.1.1 The Fleming Fund recognises the potential for fraud to occur and has robust policies and procedures in place to mitigate against this. The chosen approach follows DHSC Anti-Fraud policy, and all DHSC staff are required to complete annual counter fraud, bribery and corruption training and conflict of interest declarations. Delivery partners are also asked to complete conflict of interest declarations, with specific updates during commissioning stages. All delivery partners must adhere to HMT's guidance on Managing Public Money and DHSC fraud policy is standardised in MOU, grant, and contract templates.

5.1.2 The DHSC Anti-Fraud Unit completed an ODA Fraud Risk Assessment (FRA) following a workshop with ODA teams in February 2020. The Fleming Fund have addressed the key recommendations and have implemented mitigations to reduce fraud risk. This ensures that the Fleming Fund project team has the correct internal processes to manage any potential cases, taking a comprehensive, best practice approach with processes and controls across the full delivery chain.

5.2 Management Agent

5.2.1 As Mott MacDonald is responsible for the majority of Fleming Fund delivery and as such handle the majority of funds, particular focus has been given to ensuring they have rigorous processes and controls against the risk of loss or misuse of HMG funds with assurance conducted by DHSC via a full due diligence exercise.

5.2.2 The Management Agent ensures counter fraud measures are built into their overarching Mott MacDonald policy and governance – including having an ethics policy statement, code of business conduct, anti-fraud policy, safeguarding policy, whistle blowing process and staff training, amongst other measures. Counter fraud measures are built into programme design (i.e., country selection, eligibility criteria, due diligence and assurance, robust grant agreements and in-grant monitoring), and are implemented in practice with key Mott MacDonald expenditure controls (i.e., limited local expenditure in hubs, UK authorisations required, standard approval limits, payments processed by separate accounts payable team etc.). There are also key programme controls, which include having an experienced finance manager for grant assurance oversight, with checks and approval of quarterly technical and financial reports, spot checks of expenditure, audit of hubs by HQ against operational procedures etc.

5.2.3 To mitigate the risk to DHSC of loss or misuse of funds due to the Management Agent, the contract includes a [redacted] limit of liability. In addition, strict grantee terms have been agreed between DHSC and the Management Agent that allow recovery of funds from grantees in such

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instances. This means that if grant funds are lost or misused, the Management Agent has the ability of legal recourse in recovery of funds from grantees. DHSC are confident that no more than £50 million (given payments are made in quarters) is ever at risk at any one time.

5.2.4 There are several clauses in both the Management Agent contract and the Mott MacDonald fraud and corruption strategy that put in place robust mitigation strategies to combat the risk of fraud and corruption. Mott MacDonald also worked closely with the DHSC Grants Hub and the DHSC Anti-Fraud Unit to produce a counter fraud strategy for the Fleming Fund portfolio, which was compliant with Cabinet Office Grants Standards and guidance from a cross government panel called NGAP. The resulting document outlines the risks associated with fraud and corruption for the Fleming Fund and how these are mitigated, with reference to roles and responsibilities for DHSC and Mott MacDonald. EY also play a key role alongside Mott MacDonald in providing financial risk assurance for DHSC through a robust risk appraisal process as set out in Annex Q.

5.2.5 The Fleming Fund asset management policy follows FCDO Programme Operating Framework guidance; Mott MacDonald are required to complete an annual asset check and to maintain an asset register in line with this, and the project team requires the same process to take place at the end of the programme. Mott MacDonald also have asset registers for each Country Grant, which follow the same process. Anything valued £500 ODA or more must be included in the asset register and this must be shared with DHSC (see 2.5 section on accounting treatment for capitalization threshold).

5.3 All Other Contracts and Grants

5.3.1 For the grants the Fleming Fund disburses directly (not disbursed via Managing Agents), e.g., WHO, FAO, OIE, GRAM, CwPAMS, the DHSC Fleming Fund team operates robust financial processes and carries out due diligence. The processes followed are consistent with DHSC policies and the project team undertakes additional checks and balances for processing invoices for payment.

5.3.2 Where grants require payment in advance, this is agreed with reputable organisations, for which the relevant due diligence has been completed. This is usually for UN agencies, so the risk of loss or misuse of funds is considered low. However, on top of DHSC standard measures, the project team seeks additional assurance. For example, the recipient must provide confirmation that 80% previous disbursement has been spent or committed before the next payment can be released.

6. Fraud Monitoring and Reporting

6.1 All Contracts, Grants and Delivery Partners

6.1.1 DHSC has a zero-tolerance approach towards financial impropriety, and irrespective of the partner, there are clear provisions within grant agreements that oblige the Fund’s partners to report to the project team any financial irregularities or fraud concerns promptly along with assurances of how they will address these, and if needed, undertake any necessary investigations.

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6.1.2 DHSC has recently had a couple of fraud concerns reported, which has supported refinement of the Fleming Fund's process, and confirmed that the current procedures and mechanisms are working effectively. Alongside this, the Fleming Fund is actively taking steps to increase partner awareness of their responsibilities and promote reporting channels to encourage more openness to reporting fraud concerns. To further enhance this, the project team have strengthened the spot check process to both prevent and monitor fraud risk.

6.1.3 In the event of credible indications that UK funds may have been subject to fraud or financial impropriety, additional investigations, spot checks and/or inspections may be carried out, and DHSC reserves the ability to recover funds that have been subject to proven fraud.

6.2 Management Agent

6.2.1 Similarly, Mott MacDonald play an important role in fraud monitoring as they are responsible for the majority of Fleming Fund delivery and handle the majority of funds. The Fleming Fund have therefore sought assurance on the Management Agent's approach to fraud monitoring and reporting.

6.2.2 Financial monitoring at grant level is led by the MA's regional teams through their regional finance managers (RFMs). Depending on the nature and concern of any irregularity, the RFMs report the matter to the UK -based senior finance manager (UKFM) before investigating further with the grantee. Regional finance managers routinely pick up errors in financial reports which are computational and/or unsupported, rather than any cause for concern. Provided this is the case, and queries are satisfactorily answered, the senior finance manager and regional finance manager agree any further oversight that is necessary. This may include an increased level of 'spot checks' of physical records or a change in frequency of financial reporting where errors are considered too common.

6.2.3 Ultimately, the financial appraisal and subsequent financial monitoring of grantees should mitigate and minimise the risk of irregularities and potential for fraud, but contractual remedies are in place where relevant, should they be required. For example, to mitigate the risk to DHSC of loss or misuse of funds, the Management Agent contract will stipulate a ████ million limit of liability (see section 5.2.3 above for more detail).

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Management Case

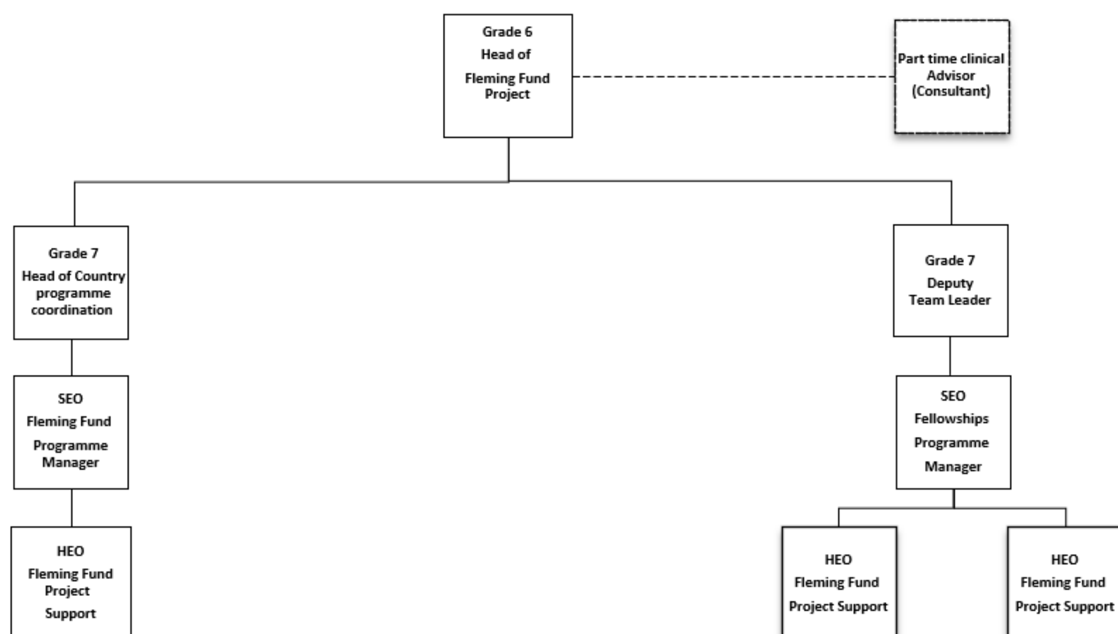
This section sets out the mechanisms in place to enable strong delivery of the Fleming Fund programme. It outlines the methodology for delivery; the governance arrangements; the monitoring, evaluation, and learning (MEL) framework; the arrangements in place for change; and contract and risk management.

1. Programme management roles and responsibilities

1.1 The Fleming Fund will be managed by a core DHSC team comprising of:

- 1x G6;
- 2 x G7s;
- 2x SEOs;
- 3x HEOs;
- 2 days a week from 1x clinical advisor;
- Specialist support as needed from wider GHS and DHSC colleagues in areas such as commercial, finance, communications, and MEL;
- 10% support from FCDO health adviser;
- Support from X-HMG evaluation network;
- Quarterly input from a twelve-person technical advisory group with specific expertise in AMR;
- 15% MEL support from a dedicated G7 MEL Advisor who provides advice and quality assurance across GHS.

Figure 5.1: Proposed Fleming Fund Staff Organogram (DHSC)



1.2 The project SRO is the same SRO for all Global Health Security projects at DHSC.

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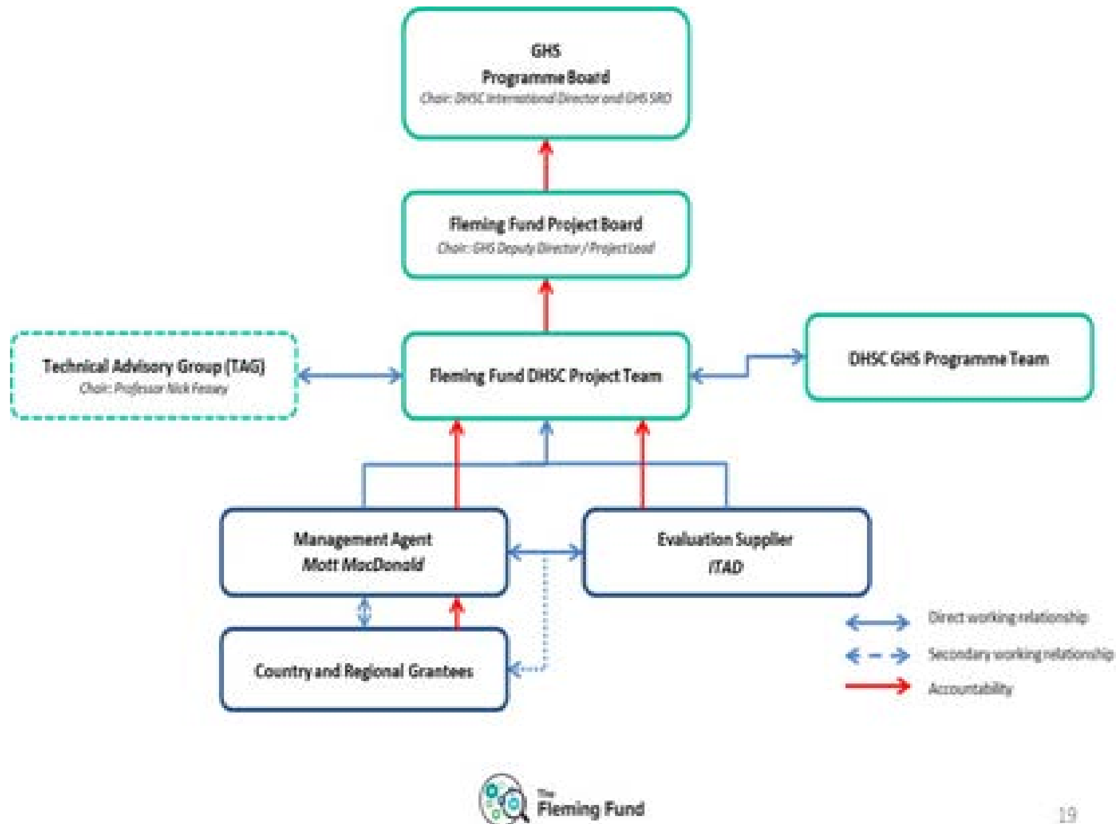
2. Governance arrangements

2.1 There are robust governance structures in place to ensure strong, accountable delivery of the programme.

Figure 5.2 Fleming Fund Governance Structure



2.2 The Fleming Fund project board is held quarterly, and comprises commercial, programme and technical experts from DHSC, FCDO, UKHSA and VMD plus external representation (see Annex S for project board Terms of Reference (ToR)). The project board provides oversight and challenge to strategy and implementation and feeds into the GHS programme board chaired by DHSC's International Director, which provides strategic oversight and direction across the whole GHS programme (see Annex T for GHS programme board ToR).

2.3 The ODA SRO Investment Committee, chaired by DHSC's Finance Director, provides internal oversight of ODA, tracks expenditure against budgets, and monitors financial risks (see Annex U for DHSC ODA governance structure and Annex V for the ODA investment Committee remit and membership).

2.4 A Technical Advisory Group of 12 external global experts working in AMR provide independent technical advice and guidance to support the strategic direction of the programme.

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3. DHSC responsibilities in managing the portfolio of all grants

3.1 Key management responsibilities for DHSC in managing the Fleming Fund programme of contracts and grants are to:

- Report on programme progress to the Fleming Fund internal DHSC project board and Global Health Security programme board (chaired by DHSC SRO);
- Liaise with Ministers and the Chief Medical Officer on programme progress and priorities;
- Ensure alignment, cooperation, and communication between various Fleming Fund grants;
- Responsible to HMT for meeting ODA annual budget targets across all strategic and programme objectives;
- Liaise with cross-government stakeholders on the programme to ensure alignment and cooperation where necessary;
- Lead the continuation of diplomatic outreach to Fleming Fund investment countries to make connections with FCDO posts and engage senior Ministry of Health officials with Fleming Fund activity;
- Draw out recommendations from the technical advisory group to support all programme objectives, in particular the portfolio of country/regional grants and fellowships;
- Ensure there are regular formal and informal, short- and long-term points within the programme cycle to identify learning, test assumptions and make necessary course corrections across the portfolio;
- Engage with other donors to ensure alignment with other actors funding AMR activities;
- Continue to monitor the value for money and likely impact of the programme;
- Manage the contract with Mott MacDonald and the Independent Evaluation Supplier, and the grant agreements with all other partners, supporting the delivery of contract and grant variations as required;
- Manage the programme through robust financial management / oversight such as profiling, forecasting, risk adjusting forecasts and implementing risk mitigations (please see 4.1 -4.13 and 6.1-6.15 of the Finance Case for details of financial management, monitoring and controls within the programme);
- Monitoring of risks and escalating to project board as needed;
- Ensuring issues of safeguarding[40] or fraud are investigated and addressed;
- Ensuring delivery against the communication management strategy;

[40] For safeguarding, the Fleming Fund project team has assessed this as a low-risk programme, but still has robust policies and processes in place to mitigate any issues of safeguarding if/when they arise

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- Establishing robust monitoring systems, and monitoring performance against indicators; as part of progress reporting, annual reviews, and project completion reviews; and
- Ensuring delivery against sustainability strategy.

4. Communications strategy

4.1 The Fleming Fund team has a comprehensive communications strategy and plan which is refreshed annually to outline the programmes communication objectives for the year; key messaging; target audiences; relevant communication channels; and programme comms calendar (see Fleming Fund Communications Strategy 2021 Annex W). Given the large portfolio of grants and stakeholders involved in the programme, there is also a stakeholder map of other key partners/donors working on AMR and/or in Fleming Fund target countries (see Annex X).

4.2 A challenge highlighted early in phase I was the issue of coordination of Fleming Fund investments at the country level. A programme of country coordination meetings has been implemented which brings together multiple stakeholders to share plans and work to improve coordination and communication of Fleming Fund investments. A coordination and engagement plan has been developed (see Annex Y) to ensure alignment both across the programme with other donors and to leverage the value of the Fleming Fund with other UK and international investment. The communications strategy and coordination and engagement plan will be refreshed for phase II of the programme. The DHSC Fleming Fund team has comms resource within the team to deliver the comms strategy and is supported by the GHS SEO comms specialist.

4.3 The Fleming Fund team has a dedicated website to support delivery of comms objectives. The Management Agent designed and hosted the initial programme website at the start of phase I. It was subsequently agreed that DHSC would contract an independent company, Softwire, to design a website fully compliant with Government digital standards and the transfer of hosting and domain names was completed in 2018. DHSC manages the website which covers the full breadth of Fleming Fund activity. The Management Agent makes considerable contributions to the content of the website in terms of the grants it manages.

5. Programme Management Approach

5.1 To effectively manage the delivery of the country, regional and fellowship scheme (through the Management Agent), the independent evaluation and all other grants, DHSC has eight key obligations and tools to draw on:

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Figure 5.3 Programme Management obligations and tools

Contractual/grant management	• Contract management plan. • Deliverables and obligations tracker. • Monthly contract performance scorecard. • Contract/grant variations to alter the obligations, costs, or terms if and when required.
Scrutiny of invoices and payment requests	• DHSC receive monthly invoices from the Management Agent and quarterly invoices from the Evaluation Supplier. Invoices are be scrutinised to ensure they are in accordance with contract charges. • Where country grants are held directly between DHSC and the relevant downstream grantees and funding is disbursed directly by DHSC, advance payment requests are restricted to one or two quarters wherever possible, with future payments only payable against expenditure statements. Only on approval of these requests are advance payments be made. • DHSC receive payment requests from all other grants which are be scrutinised to ensure they have delivered the agreed activity to date, that they have committed or spent 80% of the previous disbursement and that they require the next tranche before payment is made. These are be paid in advance in line with the payment schedule outlined in individual grant agreements (or in a Memorandum of Understanding as the Fleming Fund has with the UK FAO International Reference Centre for AMR). • DHSC conduct random invoice spot checks to support expenditure claims and ensure claims are in line with agreed expenses policies.
Regular management and progress team meetings	• Weekly management team meetings are held between the Management Agent leadership team and the Fleming Fund team. • Monthly project management meetings are held between the Independent Evaluator and the Fleming Fund team.
Monthly financial forecasting meetings	• Monthly meetings between the Fleming Fund team and the Mott MacDonald leadership team, involving DHSC Deputy Director and/or SRO as required - are held to closely review monthly financial forecasts.

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Regular reporting and review meetings	• Quarterly reports are completed (using a DHSC template). The Management Agent, Independent Evaluator, and other grantees report progress in completion of agreed activities and submit updates to results framework (including deliverables, milestones and KPIs), risk registers, and financial forecasts. • Quarterly meetings to review the submitted report, challenge where needed and agree any actions required between the two organisations in the next quarter. • Biannual reports including financial report and risk register submitted by Tripartite to DHSC.
Annual reports	• Annual reports reporting progress against results framework targets submitted to DHSC by Management agent, Independent Evaluator, and all grantees. • Annual audited financial statements submitted to DHSC by Management agent, Independent Evaluator, and all grantees
Technical advisory group meetings	DHSC can submit strategy plans, questions, deliverables, or annual reports to the Technical Advisory Group (TAG) for technical review and comment. The TAG will provide feedback intended to support DHSC with technical advice when making decisions either on management of all the grants in the Fleming Fund portfolio, their performance and progress or in the scope and direction of their work.
DHSC internal governance and assurance boards	• DHSC Fleming Fund Project Board • DHSC Global Health Security Programme Board

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5.2 In December 2016 the Cabinet Office launched new grants standards that provided guidance to government departments releasing grants. These standards were updated in 2021 (please see figure 5.4 grant standards). The Fleming Fund team will work with the DHSC Grants Hub to ensure that all funding disbursed through grant agreements are compliant with the Standard.

5.3 The Fleming Fund already has several contractual commitments in place which extend beyond phase I as these are critical to delivery of the programme as outlined in the Financial Case. To manage this transition:

- In March 2021 contract extensions were approved by the Investment Committee for the Management Agent and Independent Evaluator until March 2023.
- The GRAM grant is due to end in March 2022; the Fleming Fund will apply for a costed extension until June 2022 to enable design and transition to phase II. Approvals where needed, will be dealt with outside of the Business Case.
- Any grants which the Fleming Fund intends to continue into phase II may be subject to a costed or no cost extension to ensure a smooth transition (outlined in more detail in the Financial Case). These approvals will be dealt with outside of Business Case. The Fleming Fund project team will work with commercial and Grants Hub colleagues to develop these new agreements and renewals, to manage the transition from phase I to phase II.

6. Management Agent Roles and Responsibilities and Governance Arrangements

6.1 DHSC is not resourced or located to directly manage a large portfolio of international country grants, therefore the Fleming Fund requires an external Management Agent with a strong approach to grant and programme management and experience of successfully delivering ODA-funded programmes of this complexity and scale. Particular focus has been given to ensuring the Management Agent has robust management and governance arrangements in place.

6.2 Key management responsibilities of the Management Agent to ensure effective delivery are and will continue to be:

- Management of the relationship with DHSC including regular reporting requirements and technical input/advice on strategy;
- Managing the delivery and monitoring of the Implementation Plan (will be annexed to the contract following renegotiation);
- Financial management of the programme, including monitoring and monthly forecasting of fund requirements;
- Managing engagement with country ministries of health and other key local stakeholders on the scoping of country support, and through the life of the grants;
- Managing the request for proposals in each selected country and region, including evaluating applications, grantee due diligence and recommendations for grant award to DHSC;

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- Managing country cohorts of Fleming Fellowships, including advertisement, selection of appropriate Host Institutions and evaluation of fellowship candidates;
- Contracting and management of grantees and sub-contractors required to deliver the programme's objectives, including timely payments;
- Managing regular reporting from grantees on project and financial progress to ensure all projects are delivering their objectives;
- Work with the evaluation supplier to ensure that programme data is available for supporting the independent evaluation;
- Managing any course correction activities required, including adaptive and performance management;
- Coordination with other donors and similar/complementary projects at a country and regional level;
- Coordination with the Tripartite (WHO, FAO, OIE) at country, regional and global levels;
- Liaison with DHSC on programme communications. Manage communication of the grants programme activities and outputs, webinars and generate content for DHSC website;
- Management of four regional hubs based in Ghana, Uganda, India, and Thailand; and
- Management of country coordinators where deemed appropriate for delivery during the implementation phase.

6.3 See Annex Z for the Management Agents accountability and leadership structure with detail on the roles and responsibilities of key personnel and the Management team responsibilities.

7. Downstream Grant Management

7.1 Compliance with Cabinet Office Grants Standards

7.1.1 Cabinet Office grants standards are aimed at direct grants from HMG departments to grantees but many of the standards are applicable to downstream grants released by a third party and where these are relevant and feasible in low- and middle-income country settings – DHSC and the Management Agent will ensure compliance with the standards.

7.1.2 Figure 5.4 below illustrates key standards in the new guidelines and how the Management Agent will incorporate these into its grant management approach.

Figure 5.4 Grant Standards

Cabinet Office Grants Standard		How is it incorporated into the Management Agent and other grants approach?
Standard 1: named responsible officer for each grant	All government grants require a named senior responsible officer with clearly defined responsibilities throughout lifetime of grant.	The SRO to the Fleming Fund is overseeing the use and the management of the Fleming Fund through the governance arrangements set out in Section 1.2 – 1.3.
Standard 2: grant approvals process	Departments will ensure they have a robust grants approval process to approve spend over £100k, and that details of all current grant schemes and awards are available on the Government Grants Information System (GGIS).	The Implementation Plan sets out the grant process, applicable across all FF grants, where the grantee will be subject to review and analysis before the grant is awarded.
Standard 3: Complex grants advice panel	Complex government grants, including those that are high risk, novel, contentious or repercussive, as well as those undergoing a step change in scope or funding, should be considered for submission to the Complex Grants Advice Panel for scrutiny and advice from subject experts.	Downstream grants are subject to a thorough and robust review process, with final approval being granted by DHSC. As downstream grants are not directly made by government, the Complex Grants Advice Panel is n/a, but the process adopted by the Fleming Fund has strong oversight and governance arrangements as outlined in section 1.2-1.3.
Standard 4: Business case development	A robust business case, proportionate to the level of expenditure and risk, must be developed for all government grants. This will be scrutinised and approved in stages, as part of grants approval	FF grant applications will incorporate all required information to allow the Management Agent to review the grant proposal, expenditure, and risk.

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	process, in line with the guidance in Managing Public Money.	
Standard 5: Competition for grant funding	Government grants should be competed by default; exceptions may be approved where competition would not be appropriate. Detailed supporting evidence for any direct award decision must be provided in the approved business case.	All country and regional grants will be competed by default unless agreed otherwise by DHSC. A strong case for any exceptions where competition is not appropriate or possible will be put to DHSC for prior approval.
Standard 6: Grant agreements	All government grants shall be awarded through robust grant agreements, proportionate to the value of the grant and which reflect the Grants Functional Standard for government grants, in line with guidance in Managing Public Money. All government grant agreements shall include terms of eligible expenditure	All FF grants will be governed by an approved grant agreement, and that grant agreement will align to the requirements of MPM.
Standard 7: Risk, Controls and Assurance	All government grants should be managed within an effective and proportionate control framework, including being subject to timely and proportionate due diligence, assurance, and fraud risk assessment	All grant applications will require supporting evidence to be submitted that will allow the Managing Agent to consider the adequacy of the system of financial control, incorporating any potential fraud risk. This will inform the Fund's grant risk categorisation which will inform, in turn, the grant monitoring approach.
Standard 8: Performance and Monitoring	All government grants should have outcomes agreed and longer-term outcomes defined, wherever possible, to enable active performance management, including regular reviews and adjustments where deemed necessary	All FF grants will be governed by an approved grant agreement, and that grant agreement will incorporate the outputs mapped to outcomes through an agreed theory of change at the programme level.

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Standard 9: Annual Review and Reconciliation	All government grants should be reviewed annually at a minimum with a focus on financial reconciliation, taking into account delivery across the period, resulting in a decision to continue, discontinue or amend funding.	MM will conduct an annual review of each county grant
Standard 10: Training	All those involved in the development and administration of grant awards should undertake core training in grant management best practice.	MM and EY staff involved in developing and administering grants have experience of working in international development, and the EY team is a specialist central government financial management team familiar with all the relevant standards and best practice.

7.2 **Grant application appraisal (technical and financial)**

7.2.1 Mott MacDonald will work with AMR Coordinating Committees (AMRCCs) in country to understand the specific needs and priorities of the national AMR surveillance system and to launch a request for proposals to the market of potential grantees.

7.2.2 Grant applications will then be assessed from a technical and financial perspective, resulting in recommendations to DHSC with summaries of each grant. No grant funding will be made without DHSC's approval.

7.2.3 The Management Agents process for technical and financial appraisal of grant applications is illustrated in Annex Q (financial appraisal) and Annex R (technical appraisal).

7.3 **Downstream grant monitoring and reporting**

7.3.1 Once grants have been agreed, regular technical and financial monitoring continues at each layer of the project using a logframe type approach – a monitoring method commonly used by FCDO and other international development delivery partners.

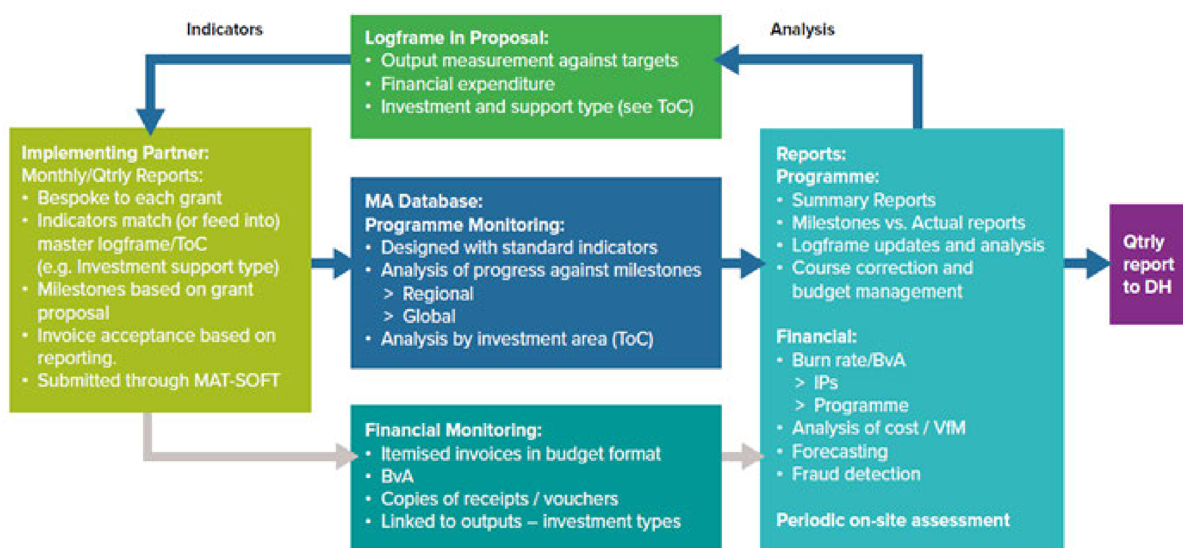
7.3.2 Grant monitoring is built around the Management Agent's Theory of Change (ToC, fig. 1.8) for the country, regional grants, and fellowships. The Request for Proposals sets out the outputs to be achieved by the grant and each of these is aligned with one or more of the investment areas shown in the ToC. This system has been replicated across all grant streams so that inputs and outputs can be tracked using a standard framework in the grant monitoring forms. In consultation with the Independent Evaluators, the Management Agent developed a separate Theory of Change for the regional grants and fellowships in 2020. The Fleming Fund would want to develop these further and refresh the country grant Theory of Change for a phase II to ensure it captures the strategic shift areas and learning from phase I.

7.3.3 The grant monitoring forms are structured around outputs and are linked to a grant budget template which is applied across all grant types.

7.3.4 Calculation of financial inputs and linkages to outputs and progress towards indicator targets can then be measured based on the financial and activity reports received from grantees on a quarterly basis, which is done routinely across all grants.

7.3.5 Figure 5.5 below illustrates the grant reporting process and cycle between grantees, the Management Agent and DHSC.

Figure 5.5 Grant reporting process



7.3.6 Grantees report on a quarterly basis using a pro-forma template preloaded with scheduled activities, outputs, and objectives. These are submitted by grantees and uploaded onto an online grant management platform (MatsSoft) where evidence of review by the regional teams, fellowship coordinator and

regional grants manager (depending on grant stream) are recorded. This allows delivery progress to be tracked on a quarterly basis.

7.3.7 Data from grantee quarterly reports is collated and analysed by the UK based Management Agent leadership team to provide management information and to report quarterly to DHSC on progress and challenges. There are also additional measures within the programme, such as KPIs, which are calculated using annual grant performance.

7.4 **Downstream Grantee performance management**

7.4.1 The grant agreement with grantees contains a number of remedial measures that the MA may take in managing grantee performance:

- The re-submission of reports;
- Revision of budgets and outputs;
- Suspension and/or discontinuation where satisfactory progress is consistently below work plans and targets and efforts at corrective actions have been met with failure.
- Non-payment of claims or recovery of previously paid claims.

7.4.2 These measures allow the Management Agent to work with the grantee where performance is a concern, including remedial actions, and ultimately, to suspend funding until such actions have been followed through and performance has been addressed. As payments are released in quarterly tranches, financial exposure is generally limited to the previous quarter's funding with full recovery of funds possible, even for previously paid claims.

7.4.3 If longer term or more serious corrective actions are necessary, then a grant improvement plan is developed that provides clear guidance and targets on what the grantee must do to rectify performance. This will aim to strike a careful balance between support and arms-length performance management of grantees. If progress continues to fall short against improvement plans, then this will trigger the necessary remedial clauses in the grant agreement. The Management Agent will raise any serious performance issues with DHSC.

8. Procurement and supply chain management

8.1 The majority of procurement activity under the Fleming Fund takes place under the Management Agent portfolio of grants, therefore particular focus has been given to ensure that the Management Agent has a robust procurement and supply chain management system.

8.2 Management Agent Procurement and Supply Chain Management (PSM)

8.2.1 Procurement has formed a significant part of the overall spend of the Management Agents portfolio of grants during phase I of the programme. While procurement spend is likely to be lower during phase II, given most countries have been equipped with key items, significant spend in this area will remain due to ongoing needs, expansion of supported sites and the addition of any new countries. The four main areas of procurement are in equipment and instruments, reagents and media, consumables, and laboratory management.

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8.2.2 The International Procurement Agency (IPA), a consortium partner of the Management Agent, is the adviser on PSM for the MA. IPA's PSM analysis focusses on identifying:

- The total procurement volume and identifying recurring procurements.
- The use of local versus central procurement – performed at country scoping and positioning activity phase of programme.
- Proportion of local procurement.
- Identify procuring body (consignee - grant recipient or subcontractor).

8.2.3 PSM decisions will take into account the following principles:

- Economy: cost comparison between local procurement and international benchmarks.
- Value: quality of existing or alternative local supply chain(s) versus international standards. Assessment will weigh up the quality of supply chain options vs their economy.
- Operational possibilities and risks: the review will consider typical but important challenges that will inform the recommended PSM route.

8.2.4 The final decision of local versus international procurement requires a careful evaluation and assessment of the various aspects and a number of related and subsequent criteria. During Phase I, the Management Agent and IPA set up a central procurement facility which secured preferential pricing for standard laboratory instruments needed in all countries. A standard procurement catalogue compiled with internationally benchmarked prices was also produced alongside a list of quality assured suppliers.

8.2.5 IPA undertook a large procurement and logistics analysis for all countries in the Fleming Fund portfolio under a regional grant. This has been used as a guidance note for grantee and countries themselves to assist in supply chain management, including consideration of the procurement timescale.

8.2.6 The Management Agent sequence of procurement and supply-chain management principles can be found in Annex AA.

8.2.7 The Fleming Fund team will work with the Management Agent to ensure lessons learnt from phase I are implemented for phase II. These include having a bespoke approach to mitigate procurement, logistical, bureaucratic, and local supplier chain challenges experienced under the phase I.

8.3 Procurement activity within other grants

8.3.1 For all other grants, the DHSC Fleming Fund team and DHSC commercial advisers will ensure that procurement risks are tested against appropriate DHSC/HMG due diligence processes and will continue to monitor these risks proportionately. Robust due diligence processes, performance reviews and in-country spot checks will be undertaken to highlight and address any issues.

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9. Performance Management of Management Agent, Independent Evaluator, and other grants

9.1 Service levels

9.1.1 DHSC have agreed a set of service levels in the contract with the Management Agent and the Independent Evaluator by which good performance will be measured. These service levels will have no financial incentive attached but rather will document the basic expectations of performance for the supplier during the implementation phase.

9.1.2 Service levels will be measured on a monthly basis and any issues in meeting these will be dealt with in monthly management meetings. The service levels agreed in 2021 will be renegotiated with the Management Agent and the Independent Evaluator (see Annex P) for phase II.

9.2 Output/Outcomes based payments and KPIs

9.2.1 As outlined in the commercial case, a proportion of the Management Agent and Independent Evaluator's fees and expenses will be subject to delivery against agreed deliverables, results and KPIs to disincentivise delays and poor performance. The proportion linked to deliverables and KPIs will be finalised at contract negotiation stage. The payment schedule for these deliverables and KPI payments will be:

- Withhold a percentage of monthly fees and expenses of the supplier as these are subject to satisfactory progress and performance;
- Review progress against deliverables at quarterly review meetings;
- If content with progress against deliverables, the monthly fees and expenses for the full quarter will be released to the Supplier;
- Review progress against KPIs at biannual review meetings;
- If content with performance against KPIs, payment will be released to the Supplier.

9.2.2 Deliverables – Quarterly deliverables will be agreed at the start of each year in an annual workplan. If required these can be amended throughout the year to allow for necessary adaptions to the project. These will be measured quarterly or biannually.

9.2.3 Results and KPIs – Results and KPIs will be agreed at the outset of phase II and the targets for each of these will be revised and will become more ambitious each year. These will be measured annually or possibly 6-monthly. The KPIs and targets for 2021 in Annex P. The portion of the retention of fees and expenses assigned to each KPI will be determined through the contract negotiation.

9.2.4 A summary of all performance management tools and the consequences of failure to meet these are listed below.

Figure 5.6 Performance Management tools

Performance Type	Determined by	Measures	Consequences
Monthly Service Levels	Head contract	Performance management indicators	Remedy under-performance Potential rectification plan process
Quarterly deliverables	Annual contract variations	Quarterly reporting milestones	Payment delay and/or non-payment of % of Fee-retention (percentage to be determined) Potential rectification plan process
Annual KPIs	Annual contract variations	Additional performance monitoring	Payment delay and/or non-payment of % of Fee-retention (percentage to be determined)

9.3 Contract and grant break clauses

9.3.1 In addition to financial incentives for performance management, DHSC will explicitly include in the Management Agent and Independent Evaluator contract one further break clause at which the Department can terminate the contract if it sees fit. Break clauses will also be included in all other grants so DHSC can terminate these if necessary.

9.3.2 The terms of these break clauses would ensure that termination of the contract would incur no further payment to the supplier after any wrap-up costs were paid in full.

9.4 Performance management of other grants

9.4.1 In line with standard 8 of the Cabinet Office Grants Standards (see figure 5.4), all other Fleming Fund grants will have outcomes agreed and longer-term outcomes defined, to enable active performance management, including regular reviews and adjustments where deemed necessary. The Fleming Fund team will work with the DHSC Grants Hub to ensure that all funding disbursed through grant agreements are compliant with this Standard.

10. Monitoring, Evaluation and Learning Framework

10.1 The following tools and mechanisms will be used to monitor, evaluate, and learn, and to hold the Management Agent and other grantees accountable for progress.

10.2 The **Fleming Fund's Theory of Change** (ToC see Fig 1.8) explains how activities are expected to produce outputs that contribute to achieving intended outcomes and impacts. It is accompanied by a narrative which provides a high-level description of how the programme expects to bring about change to achieve its desired outcomes and the assumptions and evidence that underpin how these changes are expected to occur. The ToC diagram was refined in consultation with the Independent Evaluator in 2021 to reflect learning from phase I and the phase II strategic shifts. It will be used as the foundation for the MEL framework.

10.3 **A programme wide results framework**. A results framework is a monitoring tool commonly used by FCDO and other international development delivery partners. A programme-level results framework was not in place during the design and implementation of phase I of the programme. As a consequence, each Fleming Fund grant had different monitoring metrics which meant that programme-level targets were not set and results at the programme-level could not easily be determined. Moreover, the programme did not have a systematic way to track progress towards outcomes and impact level changes. A results framework has been developed in consultation with the Independent Evaluator and delivery partners, to monitor progress against annual targets and expected results and fulfill the following objectives:

- Encourage all grants to track and report on progress in a way that is easy to aggregate up.
- Monitor progress at all levels, including at outcome and impact levels (with the recognition that interventions will only be able to 'contribute' to these higher-level results, rather than be able to 'attribute' a specific change at this level to a specific intervention).
- Provide a framework for DHSC to hold all grants to account and ensure the programme maximises its chances of contributing to the desired higher-level results

10.3.1 This has been developed in alignment with best practice from DFID's (now FCDO) 2020 Smart rules[41]. The Independent Evaluator has supported the DHSC Fleming Fund team to identify an appropriate set of indicators that will enable DHSC to track progress against the Theory of Change. The proposed set of indicators are set out in the draft results framework in Annex N. These include a menu of indicators to track progress at the level of intermediate outcomes and outputs, to allow for country variation and ownership, and where indicators already exist at the international level, they have been used to monitor progress at impact and outcome levels.

10.3.2 The results framework is still underdevelopment, more work is needed to confirm outstanding indicators, clarify the process for agreeing and tracking progress at country level, develop targets, and generate the baseline data. This will be done in consultation with international agencies and other parts of HMG over the period November – March during the phase II design period.

10.4 **The annual workplan** (broken down into quarters). This workplan will take the annual targets detailed in the results framework and break these down into quarterly milestones or activities that will be required to meet the annual targets. Workplans will be agreed at the start of each year and will be reported on at each monthly meeting and quarterly review meeting for the Management Agent and Independent Evaluator and progress meetings for other grants.

[41] FCDO (previously DFID), "Smart Rules: Better Programme Delivery", UK Government 2018

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10.5 The programme is designed **to identify learning and make necessary course corrections**. The Independent Evaluator have provided three formative evaluation reports in phase I which made several valuable recommendations that DHSC have incorporated into adaptations of the programme. These recommendations have included:

- A more efficient grant process to maximise the time for implementation;
- Increased monitoring to assess whether the Management Agent is on track to deliver outputs and is managing for effectiveness; and
- Greater in country coordination with Fleming Fund delivery partners, HMG, and other donors to avoid duplication and ensure alignment.

10.6 These recommendations have led to:

- A refined and streamlined approval processes;
- Improved monitoring and reporting to better track progress towards outputs; and
- Roll out of a comprehensive HMG engagement, particularly with FCDO posts in priority countries, running six monthly regional teleconferences, providing updates to AMR focal points and health advisers including on the links between AMR and COVID-19 (see coordination and engagement plan Annex Y).

10.6.1 The following mechanisms are in place to ensure **the programme continues to benefit from regular learning and making necessary course corrections**:

- Regular feedback loops to identify learning, test assumptions and make necessary course corrections through the annual review process, deliverables from the Independent Evaluator, quarterly review reporting, biannual strategy testing meetings, annual reviews;
- An adaptive management workplan to record and keep track of high-level strategic adaptations;
- Regular problem identification through sustainability and comprehensive stakeholder analysis and Theory of Change testing (Fleming Fund approach to political economic analysis and sustainability will be reviewed and refined as part of design of phase II); and
- Results framework to track progress against indicators and identify where adaptation may be needed.

10.6.2 Please see Annex AB for Fleming Fund's Adaptive Management approach.

10.7 The Fleming Fund project team will also undertake **an Annual Review in April 2022 with a focus on learning from phase I** to feed into the design of phase II. However as noted above, the programmes adaptive management approach means it has been leveraging lessons learnt throughout and will continue to do so.

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11. Evaluating the Programme

11.1 In phase I, DHSC contracted an Independent Evaluator to evaluate the portfolio of grants implemented by the Management Agent. The evaluation assesses how far the outputs of the portfolio of country and regional grants, and the Fleming Fellowships will contribute to the expected outcomes and impact as identified in the Theory of Change. Within this broad purpose six Evaluation Questions (EQs) were set:

- What has been the increase in the quantity and/or quality of data on Antimicrobial resistance (AMR) at country level and to what extent has the Fleming Fund contributed to this increase?
- To what extent have the Fleming Fund's investments been aligned and coherent with other relevant investments at country level?
- How likely are the Fleming Fund's country level results to be sustained?
- Has, or is it likely that, the increase in AMR data influenced: (a) changes in national policies/regulations?; and/or (b) changes in practice and attitudes in country?
- What has been the increase in quality data shared and reported internationally and has the Fleming Fund contributed to this?
- Did the Fleming Fund's investments at country level offer value for money?

11.2 The Independent Evaluator is also contracted to evaluate the Global Research on AMR (GRAM) project to support learning by the funding and implementation partners and to test the effectiveness of the approach deployed.

11.3 The purpose of the evaluation is both formative and summative. In the period 2016-2020, the evaluation focused on generating learning to enhance the quality of implementation. In 2021, the balance shifted to provide a summative judgment that answers the EQs

11.4 The plan is to extend the Independent Evaluator’s contract in phase II to a programme wide evaluation to cover the full breadth of Fleming Fund activity for a more consistent and coherent MEL approach across the fund.

11.5 The Fleming Fund is no longer a novel programme, it has over 3 years of implementation experience and has learnt and made necessary course corrections through phase I. The project team are now confident in the model of the Fleming Fund, so the scope of the evaluation would be reduced to focus more on assessing achievement of outcomes, impacts and value for money. The scope of the evaluation for a phase II will be:

- Programme wide evaluation to cover grants delivered by the Management Agent and all other grants;
- One formative deliverable at mid-way point, with a focus on the strategic shift areas (including: One Health, use of data and building the economic case) to support adaptive learning;
- One summative deliverable at the end of the programme to answer the 6 EQ’s but with the addition of questions which assess the strategic shift areas the

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exact wordings of these strategic shift EQs will be agreed with the independent evaluator; and

- A smaller sample of countries in proportion with the evaluation.

11.6 To ensure the EQs are effectively answered throughout the project lifetime and at the end of the funding cycle, the Fleming Fund will negotiate increased onus on the Management Agent to monitor and evaluate themselves with additional MEL resources to fulfil this. The Independent Evaluator will work with the Management Agent to support the design of a regular monitoring strategy for country/regional grants and fellowships. With this monitoring strategy in place, the Management Agent will collect data through grantees, which can be used to answer evaluation questions when needed. The Independent Evaluator will also collect any additional data needed and conduct site visits to verify the data collected by the Management Agent, to answer the agreed evaluation questions.

12. Transparency

12.1 The Fleming Fund will publish data in line with the International Aid Transparency Index (IATI) and DHSC standards that are informed by FCDO guidance on transparency reporting. The Fleming Fund will continue to meet the criteria for supporting the DHSC index ranking of ‘good’ or ‘very good’ via regular publication of relevant key documents on Dev Tracker. The Fund is committed to openness, scrutiny, and accountability and this will ensure information on resource flows and key programme documentation is publicly available. In addition, as part of the programme, the project team will encourage implementing partners to meet global transparency standards.

12.2 The Management Agent will be required to provide information and documentation to DHSC in a timely manner to facilitate assessment of the programme’s performance against the IATI standards.

12.3 The Fleming Fund website will provide a range of publicly accessible project information, and act as a key communication and reference tool for policy makers, partners, AMR Networks and OGDs.

12.4 DHSC has embedded effective learning processes, both within health projects and across other ODA departments. The 2019 ICAI review on How UK Aid Learns also found DHSC to be agile, sharing learning between its ODA and non-ODA portfolios and facilitating two-way learning with FCDO.

12.5 In the 2019 UK Aid Transparency Review, DHSC was one of only two UK government departments (alongside DFID, now FCDO) awarded the highest ‘Very Good’ rating with a score of 82.1. This represented a significant achievement for DHSC in its first UK Aid Transparency Assessment. The Department was praised for publishing good quality, detailed information about its aid spending policies and projects, which allows for its ODA expenditure to be scrutinised, learned from, and improved through public accountability. The Fleming Fund is committed to maintain and improve on this high standard of transparency during phase II.

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13. Managing Risk across the Programme

13.1 Department for Health and Social Care risk management and methodology.

13.1.1 The DHSC Fleming Fund team exercises a robust approach to risk management. This entails:

Figure 5.7 DHSC Fleming Fund team risk management approach

Contract/ grant level risk register	Management Agent and Independent Evaluator required to submit updated risk register to DSHC Fleming Fund team on a quarterly basis. Quarterly meetings to review the submitted risk register, challenge where needed and agree any actions required in the next quarter. Risks are reported by all other grantees in quarterly and 6 monthly progress reports and are discussed in progress review meetings.
Fleming Fund programme level risk register	Maintenance of a live programme risk register updated on a regular basis (at a minimum monthly) by delegated leads across the Fleming Fund. Programme level risks and mitigating actions are reviewed and approved on a quarterly basis by the project board, chaired by an SCS1 Deputy Director. Where risks cannot be managed with confidence, or mitigating actions defined, within the project team or board due to lack of internal expertise or capacity, they may be shared with a broader peer network of advisers across government with the relevant expertise to advise on an appropriate course of action, (for example with Defra in regard to Animal Health).
GHS Programme level risk register	Where risks meet a defined threshold, they are recorded in the programme level risk register and escalated to the GHS programme board, chaired by an SCS2 Director, for review and decision on appropriate mitigating action.
Country level and regional risks	Co-produced by Fleming Fund team and the Management Agent and shared on a quarterly basis at project board. Helps to increase visibility and management of country specific and wider political and environmental risks which is monitored by Fleming Fund's project board. Desk-based assessments are conducted of each country's context, AMR status, and political and operational risk in relation to the objectives of the programme.
Joint risk register	Co-produced by Fleming Fund team and the Management Agent on a quarterly basis. Sets out mitigating actions and an assessment of the residual risk is made. Focuses on key risks to the programme and the mitigating actions for either the MA or DHSC, or both, to own and manage. Covers delivery risks, as well as broader performance and contractual risks.

13.1.2 Risks are assigned a score and overall risk rating (Red/Amber/Green category) according to the standardised GHS risk scoring methodology.

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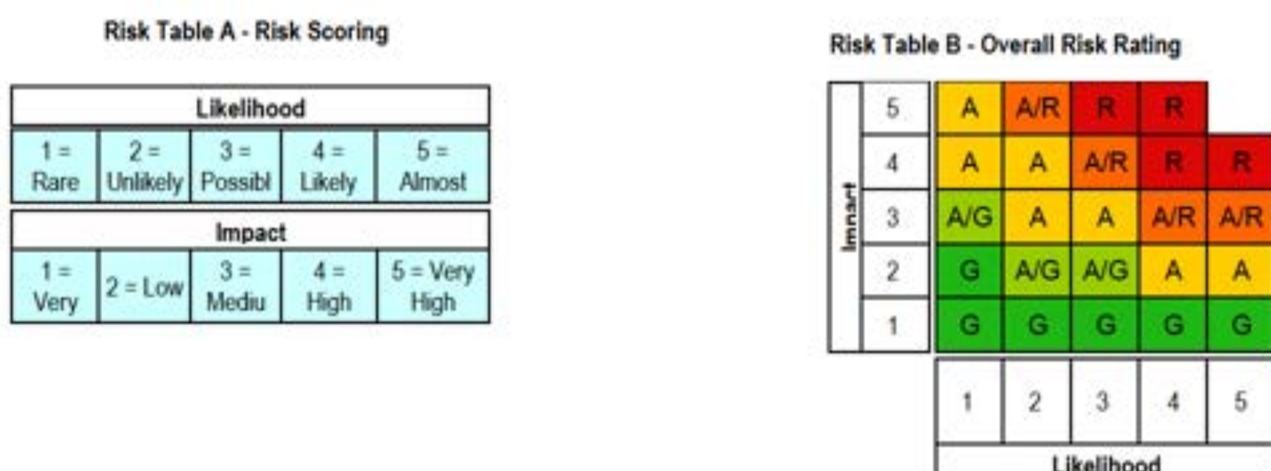
13.1.3 The escalation of risks to the programme board is at the discretion of programme lead in agreement with the project board. However, there is a general expectation that risks meeting one or more of the following criteria would be escalated to the programme board, chaired by an SCS2 Director, for resolution or review:

- Risks that are red rated (i.e., have a risk scoring of greater than 15)
- Risks that pose significant reputational impact for the programme or Department
- Risks which might have a significant financial impact on the wider GHS programme should they come to fruition.

Figure 5.8 DHSC GHS Risk Rating



Risk Table A - Risk Scoring

Likelihood				
1 = Rare	2 = Unlikely	3 = Possibl	4 = Likely	5 = Almost
Impact				
1 = Very	2 = Low	3 = Mediu	4 = High	5 = Very High

Risk Table B - Overall Risk Rating

Impact	Likelihood 1	2	3	4	5
5	A	A/R	R	R	
4	A	A	A/R	R	R
3	A/G	A	A	A/R	A/R
2	G	A/G	A/G	A	A
1	G	G	G	G	G

13.2 Management Agent risk management methodology

13.2.1 Grant level risk management is devolved to the Management Agent with high level programmatic risks escalated to DHSC. The Management Agent outlined their risk mitigation procedures for phase I in the implementation plan along with the escalation method of risks from grantee to regional hub to MA leadership team to DHSC, this will be reviewed in the design of phase II.

13.2.2 Programmatic risks at a grant level are captured in the form of a standard risk register contained within grant applications and reported by grantees on a quarterly basis these include measures to counter fiduciary risks.

13.2.3 Risk management has been built into the programme design in the following ways:

- Country level and regional risks - The selection of priority countries was based on a desk-based assessment, conducted on each country's context, AMR status, and political and operational risk in relation to the objectives of the programme.
- Grant development and selection process – the Management Agent's framework for designing grants and selecting grantees is a tightly controlled process which:
    - Validates country selection;

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    - Sets clear parameters on eligibility for funding;
    - Engages with countries to ensure ownership and supports preparatory work; and
    - Limits initial financial exposure through appropriate size grants.
- Grant management and financial monitoring documents – set out the due diligence, grant assurance, technical and financial monitoring, and procurement approach. Grantees will be assessed against standards for risk as part of initial eligibility criteria and monitored over the life of a grant.
- Reporting and performance management – provides the service levels and KPI's against which the Management Agent will be accountable.

13.2.4 The Management Agent continues to identify and manage risks through the life of grants using the joint risk register and internal risk management processes which include training, safeguarding and routine reviews.

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