Australian Government
Department of Foreign Affairs and Trade

Australian Aid

PRODUCT DEVELOPMENT PARTNERSHIPS FUND: MID-TERM REVIEW

FINAL: 8 October 2020

CONTENTS

ACRONYMS

ACT-Accelerator: Access to COVID-19 Tools Accelerator

AMR: Anti-microbial resistance

APLMA: Asia Pacific Leaders Malaria Alliance Secretariat

APMEN: Asia Pacific Malaria Elimination Network

ASEAN: Association of Southeast Asian Nationals

BMGF: Bill and Melinda Gates Foundation

CEPI: Coalition for Epidemic Preparedness Innovations

CHS: Centre for Health Security, Australian Department of Foreign Affairs and Trade

COVAX: Vaccines pillar of the ACT-Accelerator

DFAT: Australian Department of Foreign Affairs and Trade

DFID: Department for International Development, UK

FIND: Foundation for Innovation New Diagnostics

HSI: Health Security Initiative for the Indo-Pacific Region, Australian Department of Foreign Affairs and Trade

IVCC: Innovative Vector Control Consortium

LMICs: Low to middle income countries

MMV: Medicines for Malaria Venture

MRI: The Bill and Melinda Gates Medical Research Institute

PDP: Product Development Partnerships

PDPFG: Product Development Partnerships Funders' Group

PNGIMR: Papua New Guinea Institute of Medical Research

R&D: Research and development

RSP: Regulatory Strengthening Program

SEARO: WHO South East Asia Regional Office

TB: Tuberculosis

TGA: Therapeutic Goods Administration

THAI FDA: Thai Food and Drug Administration

TPP: Target Product Profile

US FDA: United States Food and Drug Administration

VCAP: Vector Control Platform in Asia Pacific

VCT: Vector control tool

WHO: World Health Organization

WPRO: WHO Regional Office for the Western Pacific

1. EXECUTIVE SUMMARY

This is the Mid-Term Review Report for the Product Development Partnerships (PDP) Fund which is being implemented as part of the Australia Government's Health Security Initiative for the Indo-Pacific Region (HSI) by the Centre for Health Security (CHS).

Background

The PDP Fund was established in 2018 as part of DFAT's Health Security Initiative for the Indo-Pacific region. Its objective is to accelerate the development of new and effective tools for tuberculosis (TB), vector (mosquito) borne diseases including malaria, and emerging infectious diseases, in order to contribute to a reduced disease burden in Southeast Asia and the Pacific. This aligns with the HSI Strategic Framework.

The Department of Foreign Affairs and Trade (DFAT) allocated AUD$75million over five years (mid-2018 to mid-2023) to support the work of four PDPs: Medicines for Malaria Venture (MMV), TB Alliance, Foundation for Innovative New Diagnostics (FIND) and the Innovative Vector Control Consortium (IVCC) (referred to in this report as 'the PDPs'). Each PDP has been allocated AUD$18.75million over this period through the PDP Fund. In May 2020, FIND was allocated a further AUD$7.5million to support its COVID-19 response. In addition, DFAT provided AUD$4.5million in funding to the Coalition for Epidemic Preparedness Innovations (CEPI) in support its core work for three years to December 2022. In May 2020 DFAT awarded CEPI a further AUD$7.5million towards the development of COVID-19 vaccine candidates. The CEPI and FIND COVID-19 funding, and the CEPI core funding, was additional funding and not drawn from the PDP Fund. However, this funding is included in the report.

The PDP Fund builds upon DFAT's previous investment in PDPs from 2013 to 2018. This PDP Fund includes vector control for the first time as well as greater coordination with other DFAT-funded investments, both recommendations from an evaluation of the previous phase of PDP funding.

The Operating Context

The biggest change to the operating context for the PDPs has been the advent of COVID-19. This has and will have a four-fold impact on the work of PDPs: 1) PDPs currently anticipate delays in some activities, particularly clinical trials, of between 3-9 months. Impacted activities have been pivoted where possible. 2) Some of the PDPs, primarily FIND and MMV, have been significantly involved in the COVID-19 global response, including co-leading the diagnostics pillar of the Access to COVID-19 Tools (ACT)-Accelerator (FIND), increasing pressure on their capacity to progress their existing work 3) It is anticipated that COVID-19 will reverse some of the gains made in diseases such as TB and malaria, and 4) There is potential that funds available to PDPs will either be reduced or diverted as a result of the pandemic (due to the economic downturn and/or diversion of resources to address COVID-19); or conversely, there is a possibility that funding may increase due to a renewed interest in global health research and development (R&D).

The Mid-Term Review

This Mid-Term Review covered the initial period of the PDP Fund from mid-2018 to the end of 2019. It had both a retrospective and prospective component. The objectives of the review were:

Retrospective

1. Assess the progress of FIND, TB Alliance, MMV, and IVCC against their contracted activities to inform DFAT's decision on the value of funding tranches 4 and 5
2. Assess the overall progress of the PDP Fund against the design and its contribution to the broader objectives of the HSI

Prospective

3. Provide guidance as to key products of focus and areas of engagement with the PDPs going forward.

The primary audiences for the review were CHS and the PDPs, with secondary audiences being those involved in product development and access. The review was conducted from May to August 2020 by Kathryn Dinh, Monitoring Evaluation and Learning (MEL) Consultant to the Centre for Health Security, in consultation with the CHS PDP Fund Program Managers. Work on the review coincided with the PDP study conducted for DFID and the PDP Funders Group (PDPFG), and some results have been triangulated with the study's Preliminary Report.

The key components of the review methodology were a document review (n=110) and semi-structured interviews with 32 representatives from the PDPs, CHS staff, other funders, HSI-funded program partners, the private sector and another product development model. A thematic analysis was conducted, and interview and document evidence triangulated. Testing and validation sessions were conducted with CHS Program Managers and CHS Management.

The Results

1. PDP Progress

The PDPs achieved significant milestones during the 2018-2019 period. MMV registered tafenoquine through USFDA and TGA, the first new treatment for the radical cure and prevention of *P. vivax* malaria in 60 years. TB Alliance obtained approval for pretomanid as part of the BPaL regimen (bedaquiline, pretomanid, linezolid) which significantly reduces treatment time and cost for highly drug resistant forms of TB. FIND secured EU regulatory approval for its SILVAMP TB LAM test for people living with HIV and children and IVCC completed technical, regulatory and market access landscaping studies in the Indo-Pacific. It is noted that roll out of these new products is not automatic, and there are still challenges and product concerns that need to be addressed.

This review found that all the PDPs had made sufficient progress to the end of 2019 against the activities described in their funding agreements, with any delays appropriately explained and initial provision made to recoup time in 2020. However, the final impacts of COVID-19 on PDP activities is still unknown. At the end of 2019, the PDPs had completed development of the following number of products: 13 (MMV), 6 (TBA), 24 (FIND) and 5 (IVCC). They also demonstrated evidence of access-related activities for their products, such as their inclusion in WHO guidance and/or being granted regulatory approval. The PDPs were able to provide some examples of product distribution, such as > 50million FIND-supported products distributed since 2015.

The degree to which PDPs were addressing gender equality in their work was variable, with strong examples in MMV's strategy for earlier testing of suitability in pregnancy and studies by all PDPs on the gendered impacts of treatments/diagnostics. Addressing gender equality could be strengthened for all PDPs.

The review found continued evidence that the PDP model represents value for money as well as PDP-specific examples of the large-scale health and economic impacts of their work. The cost effectiveness of the PDP model was reaffirmed by the DFID/PDPFG study.

2. PDP Partnerships and Collaborations

The PDPs have developed significant partnerships and collaborations with Australian institutions. This has had mutual benefit, with the PDPs gaining from the Australian institutions' technical knowledge and networks, and the PDPs contributing their impact-orientated focus. Similarly, PDPs have developed formal collaborations and regular communication with several HSI-funded programs/partners, such as the Regulatory Strengthening Program (implemented by the Therapeutic Goods Administration-TGA), the Burnet Institute and the Asia Pacific Leaders Malaria Alliance (APLMA). These collaborations have served to strengthen or facilitate operational research related to product development and/or accelerate progress along the product access pathway.

3. DFAT Engagement and Support

The review found that the PDPs universally appreciated their positive working relationships with CHS staff. In addition to the provision of funding, DFAT was able to support and engage with the PDPs in three key ways: 1) Brokering relationships with other HSI programs, Australian institutions and other actors in the Indo-Pacific 2) Providing contextual knowledge of the region 3) Providing strategic input and leadership, particularly through the PDPFG and the CEPI Investors Council.

4. COVID-19 Response

In March 2020, CEPI, Gavi and the WHO were designated co-leads of the vaccines pillar of the ACT Accelerator – COVAX – which aims to deliver up to two billion doses of a COVID-19 vaccine by the end of 2021. DFAT funding is contributing towards this effort. A number of the PDPs have also been contributing to the COVID-19 response, including FIND's co-lead, alongside the Global Fund, of the diagnostics pillar of the ACT-Accelerator and MMV's co-lead of the WHO Supply and Commodity Workstream for the malaria COVID-19 response.

5. Future Trends

Key trends identified in this review include: an increasing role of PDPs in product access; an appetite across groups of stakeholders for a critical pathway approach to addressing access barriers by leveraging the relative strengths of multiple actors; and a confluence of actors and initiatives (including KOICA, ADP, GHIT and Uniting Efforts) working on product development and access issues in the Indo-Pacific, including issues that are the focus of several HSI-funded activities.

6. Management Actions

Some of the key CHS management actions arising from this review for both the remainder of the current funding period as well as a potential future period of funding were:

6.1 Current Funding Period

- **Continue to fund the PDPs for the remainder of the current funding period at the same level** and monitor progress of activities and financial reporting.
- Work with the PDPs and other partners in the region to map **critical pathways** to enable **access** for specific products, identifying actors best placed to support at key points including DFAT.
- Ensure that the PDPs continue to regularly **report** on the **impacts** of **COVID-19** on their progress.
- Link PDPs with relevant **advice** on strengthening their ability to address **gender equality**.
- Contribute to ongoing efforts to strengthen the **quality** and **consistency** of **PDP MEL** and **reporting**.
- **Meet** with the **Burnet Institute** on a **periodic basis** to coordinate and leverage activities.
- Continue to find opportunities to broker linkages between PDPs and **Australian institutions.**
- Continue to strengthen **linkages** between PDPs and other **HSI-funded investments**, in particular RSP.
- Increase communication exchange with **Unitaid, BMGF, KOICA, GHIT and ASEAN** on access issues.
- Continue to provide **leadership** and **strategic input on product development and access**, particularly through the PDPFG.

6.2 Future Phase of Funding

- Consider re-orientating some future CHS funding to place **greater emphasis on end-to-end solutions which include demand-driven access activities.**
- **Core funding** or equivalent **funding flexibility** should be maintained for PDPs.
- Conduct an assessment of the progress and outcomes of **newer product development models** and review the operation of other Australian R&D funding to inform how Australia invests in product development going forward.
- Continue to fund **regulatory strengthening activities** in the Indo-Pacific.
- Continue contributing to the development of, and participation in, **formal global and regional governance and coordination structures for product development and access.**

2. INTRODUCTION

This is the Mid-Term Review Report for DFAT's Product Development Partnership Fund (PDP Fund). Product Development Partnerships (PDPs) are non-profit entities that bring together the public and private sectors to research, develop and support access to new products that target diseases disproportionately affecting low to middle income countries (LMICs).

The PDP Fund

As part of the Australian Government's Health Security Initiative for the Indo-Pacific region (HSI), DFAT established a PDP Fund. The objective of the fund is to accelerate the development of new and effective tools for tuberculosis (TB), vector (mosquito) borne diseases including malaria, and key vaccine preventable diseases, in order to contribute to reduced disease burden in the Indo-Pacific. This objective is in line with the HSI Strategic Framework. DFAT allocated AUD$75million over five years (mid-2018 to mid-2023) to support the work of four PDPs: Medicines for Malaria Venture (MMV), TB Alliance, Foundation for Innovative New Diagnostics (FIND) and the Innovative Vector Control Consortium (IVCC). Each PDP has been allocated AUD$18.75million over this period through this PDP Fund. This makes Australia approximately the fourth or fifth largest funder of each of the four PDPs [1]. In addition, in May 2020 FIND was allocated AUD$7.5 million to support its COVID-19 response, separate to the PDP Fund. These funds are being managed through the Centre for Health Security (CHS), which implements the HSI. The PDP Fund represents a continuation of aid program funding to PDPs, following a previous allocation of AUD$40 million for the period 2013-18.

While not funded under the PDP Fund, DFAT's support for the Coalition for Epidemic Preparedness Innovations (CEPI) has been managed alongside the PDP Fund and this work has been included in sections of the report. DFAT awarded CEPI AUD$4.5million to support its core work for three years to December 2022 and in May 2020, DFAT awarded CEPI a further AUD$7.5million towards the development of COVID-19 vaccine candidates.

The Product Development Partnerships

MMV was launched in 1999 as a PDP for antimalarial drug research. To date it has developed and brought forward 13 new medicines and it is estimated that 2.2 million lives have been saved by MMV-supported drugs. MMV has over 150 active global partnerships. TB Alliance was launched in 2000. In 2019, TB Alliance became the first non-profit organisation to develop and register an anti-TB drug. It currently partners with 500 organisations and has developed six new anti-TB drugs. FIND was established in 2003 and develops new diagnostic tests for diseases of poverty. To date it has developed 24 new diagnostic technologies and works with many partners. FIND is currently co-leading on diagnostics for the Access to COVID-19 Tools (ACT) - Accelerator a WHO-global collaboration for the development, production and equitable distribution of vaccines, therapeutics and diagnostics for COVID-19. IVCC was launched in 2005 and develops vector control technologies (VCTs) to prevent the transmission of vector-borne disease. IVCC works with many academic and industrial partners and has developed 5 VCTs since its launch. CEPI is a global partnership that was established in 2017 to develop vaccines to stop future epidemics. It is the co-lead of the vaccines pillar of the ACT-Accelerator.

The Mid-Term Review

The Mid-Term Review of the PDP Fund had two components: a *retrospective* component examining the progress of the four PDPs and describing the involvement of the PDPs and CEPI in the initial COVID-19 response; and a *prospective* component to identify potential areas for DFAT engagement in product

[1] This is approximate only as funders' contributions to PDPs cover different time periods and, in some instances, there is more than one funding stream from a single donor or government.

development and access going forward. The retrospective component covered the period from mid-2018 to end 2019, although discussion of the implications of COVID-19 has been included.

As such, the review had the following objectives:

Retrospective

1. Assess the progress of FIND, TB Alliance, MMV, and IVCC against their contracted activities to inform DFAT's decision on the value of tranches 4 and 5.
2. Assess the overall progress of the PDP Program against the design and its contribution to the broader objectives of the HSI

Prospective

3. Provide guidance as to key products of focus and areas of engagement with the PDPs going forward.

The review was also tasked with revising the program logic and Monitoring, Evaluation and Learning Framework (MELF) for the PDP Fund and preparing a case study.

Eight evaluation questions guided the review design and data collection. These were:

EQ1: What progress have the PDPs made against their agreed **contractual activities**?

EQ2: What progress has the PDP Program made towards achieving its **objectives** and contributing towards improving the **response to infectious disease threats** in the Indo-Pacific region?

EQ3: Have DFAT's PDP investments performed sufficiently effectively to warrant the planned **continuation of funding** for a further two years?

EQ4: What would be required in the design of a **MELF** for the PDP Program so that it is realistic and achievable, and contributes to the broader monitoring of the HSI?

EQ5: Based on both CHS and PDPs' existing resources, **can engagement with PDPs be optimised further** to strengthen impact of their work in Southeast Asia and the Pacific – and if so, how?

EQ6: What evidence is there that the **PDP model is sustainable,** and that **progress** is being made along all stages of the **medicine development to market pathway**?

EQ7: How has the PDP Program contributed to greater **gender equality** and ensured that gender equality considerations have been integrated into PDP activities?

EQ8: What are some of the key **trends in funding for the medicine development to market pathway** that could inform DFAT's future strategic direction, focus on key products and discussions with partners?

Where a section of the report addresses a particular evaluation question, the question number is noted in brackets [EQ].

The primary audiences for the review were the CHS Management Team, CHS PDP Fund Managers and PDPs funded through the HSI. Secondary audiences include stakeholders involved in product development and access, particularly those working in the Indo-Pacific.

The review was undertaken by Kathryn Dinh, Monitoring, Evaluation and Learning Consultant and Senior MEL Advisor to CHS, from May to August 2020 in consultation with the Program Managers for the PDP Fund at CHS. It was guided by the DFAT Monitoring and Evaluation Standards (2017) which sets out requirements

for evaluations of DFAT investments. The review is a continuation of DFAT's process for monitoring its PDP funding, with the previous final evaluation of DFAT's last round of PDP funding occurring in November 2017.

This report

This report is structured as follows. Sections 3 and 4 outline the operating context for the PDPs and the review methodology used. Section 5 examines the progress of the PDPs. Sections 6 and 7 look at the PDP partnerships and collaborations, as well as DFAT's engagement with and support of the PDPs. Section 8 looks at COVID-19 response and impacts. Section 9 explores future directions in product development and access. Sections 10 and 11 provide conclusions and management actions for DFAT for the current funding period and beyond. The evaluation questions addressed by each section are noted in brackets.

3. CONTEXT

Undoubtedly the greatest challenge in the operating environment for the PDPs recently has been the emergence of COVID-19. This has required a significant increase in activity for FIND as Co-Lead of the Diagnostics Pillar of the ACT-Accelerator and the other PDPs have also been contributing to the COVID-19 response. At the time of this report, PDPs estimated delays of between 3-9 months on some product development activities due to the impacts of COVID-19, including delays in clinical trials. The final impact on activities is unknown. It is anticipated that the pandemic will have long-term impacts on the progress made to combat diseases such as TB and malaria and this, together with the necessary surge in donor funding for COVID-19 and the downstream economic impacts of the virus, has created a highly uncertain operating environment for PDPs. However, the unprecedented and rapid organisation of the ACT-Accelerator could result in valuable lessons learnt about international collaboration and coordination of actors involved in product development and access. *See Section 8 for further discussion on COVID-19.*

There have been other significant changes in the PDP operating context in recent years. First, the blurring of boundaries between the role of the PDP and product sponsor in supporting product access, with an increasing role being played by the PDP. Second, an increased recognition by donors and others of the need to support product access and a corresponding growth in initiatives to discuss and support this. However international efforts have been disjointed and there is now a strong appetite for well-led and coordinated global action in access. Third, the growth in alternative models for product development, such as Bill and Melinda Gates Medical Research Institute (MRI), GHIT and the RIGHT Fund, which are in some cases working together with PDPs.

See Section 9 for more detailed discussion of these and other changes in the PDP environment.

4. METHODOLOGY

4.1 METHODOLOGY

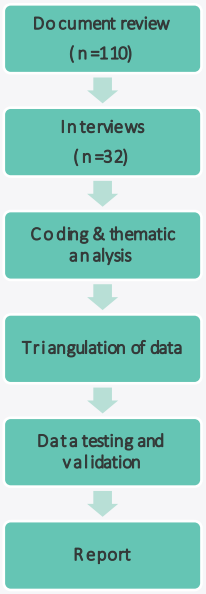
At the outset of this review, evaluation questions were identified to guide the review design and data collection tools. An evidence matrix was developed to collect data against the evaluation questions as well as to track the progress of the PDPs against a Monitoring, Evaluation and Learning Framework (MELF) updated for the PDP Fund ahead of the review.

A document review of approximately 110 documents was conducted to collect evidence against the evaluation questions as well as to identify evidence gaps that could be addressed by the interviews. The documents included PDP reports, planning and presentation documents, grant agreements, papers on R&D trends, meeting minutes, scientific papers and email correspondence.

Interviewees were identified by the Evaluator together with the PDP Fund Program Managers against a set of criteria to ensure a diversity of informed perspectives. Tailored semi-structured interview guides were used (see Annex 3).

A total of 32 people were interviewed: PDPs (12), CHS staff (6), other funder (5), HSI-funded program/partner (6), private sector (2), other product development model (1)[2]. In many cases, more than one representative from an organisation was interviewed.

Figure 1: PDP Review Method



Thematic analyses were conducted to identify patterns within the collected data. The document and interview data were then triangulated to validate findings. Preliminary findings and management actions were tested and validated in meetings with CHS Program Managers and Management (Figure 1).

4.2 LIMITATIONS

This review relied heavily, and in some instances solely, on the evidence provided by PDPs to report on their progress. It would have been preferable to independently verify this evidence, but within the scope of the review this was not possible. The timing of the review, during the COVID-19 pandemic, limited the availability of some stakeholders for interview, so the views of some important actors in the region, such as representatives from the WHO Regional Office for the Western Pacific (WPRO) and WHO South-East Asia Regional Office (SEARO), were not able to be represented.

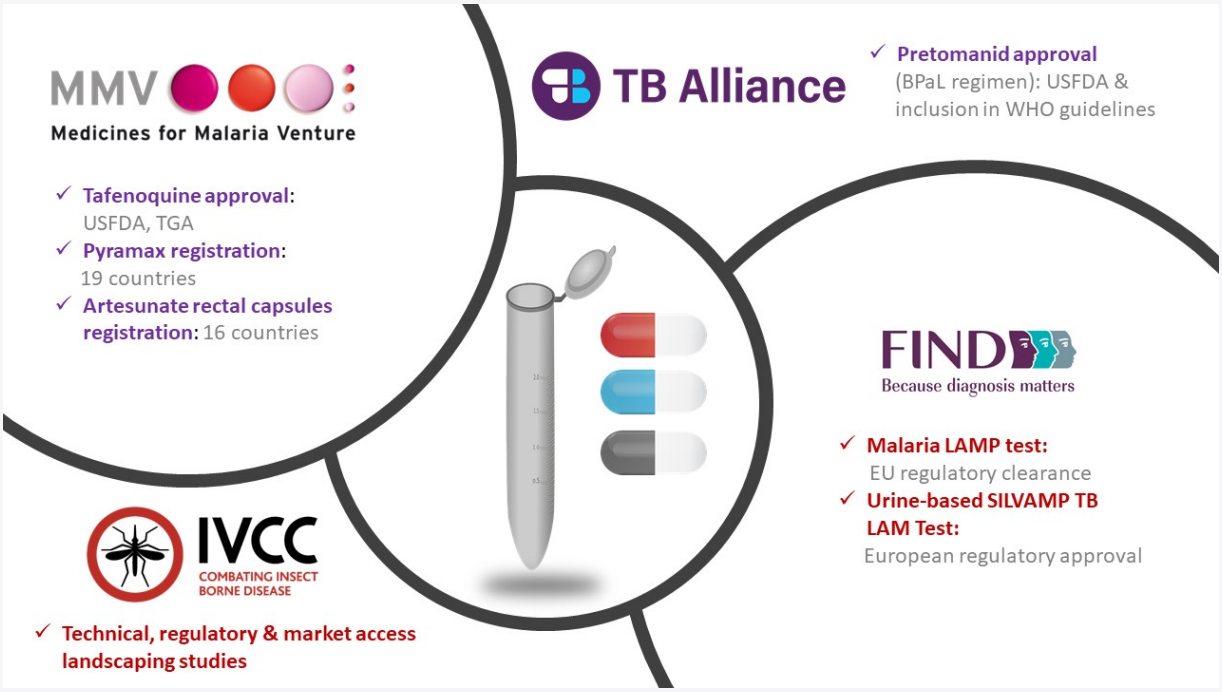
[2] Two of the people interviewed were from the Bill and Melinda Gates Foundation but also answered questions on the Bill and Melinda Gates Medical Research Institute. However, they have only been counted once in the 'other funder' category.

5. PDP PROGRESS

5.1 KEY ACHIEVEMENTS

This section highlights some key achievements of the PDPs in areas of work being funded by DFAT during 2018-2019.

Figure 2: Key Achievements of PDPs 2018-2019



MMV: Approval of tafenoquine (Krintafel/Kozenis) by US FDA and TGA (2018) and marketing authorization applications approved in Brazil and Thailand (2019). This is the first single-dose treatment developed for the radical cure of *P. vivax* malaria. However there have been some concerns about some adverse events associated with tafenoquine, especially for people with G6PD deficiency. In planning for roll-out, MMV has been working with WHO and others to address appropriate post-market surveillance and availability of G6PD testing.

: Registration of Pyramax® (pyronaridine–artesunate) granules in 19 African countries; approximately 600,000 patients were treated with Pyramax in 2019.

: Registration of artesunate rectal capsules for the pre-referral management of severe malaria in children in 16 countries

TB Alliance: Approval of pretomanid as part of the BPaL (bedaquiline, pretomanid, linezolid) regimen for drug resistant TB by the US FDA in August 2019 and immediate inclusion in WHO guidelines. BPaL aims to reduce treatment time from 2 years to 6 months and increases treatment success from 16 to 89 per cent. It generally reduces the cost of treatment by 40–50 percent, and specifically reduces the cost of successful treatment by over 65–80 percent. WHO guidance enables treatment with BPaL during operational research.

FIND: The Malaria-LAMP test received EU regulatory clearance. This is the first molecular test to detect malaria caused by *P. vivax* parasites even in low-transmission settings.

: Urine-based SILVAMP TB LAM test with Fujifilm was accepted for international use through European regulatory approval. It aims to address an unmet need for people with HIV and children who can have difficulty producing sputum.

IVCC: Completion of technical, regulatory and market access landscaping studies in 2019 to map in detail the Indo-Pacific environment. The mapping included details on the consumer market size, donor activities and regulatory routes to market for vector control tools. The Indo Pacific Initiative Advisory Group was also formed, along with partnerships for testing products in PNG (NATNAT) and in Cambodia and Thailand (Project BITE).

5.2 PROGRESS AGAINST CONTRACTUAL ACTIVITIES [EQ1]

Each PDP funding agreement signed in mid-2018 contained an Activity Proposal. While DFAT is providing core funding, these activities highlighted priority disease areas for DFAT and monitoring their progress provides an indication for DFAT of the progress of the PDPs as a whole. As part of the review, progress against these activities was assessed against information provided in PDP reports and interviews.

As at the end of 2019, the PDPs reported reasonable progress against the contractual activities, given the mid-way point in the funding period (see Table 1). Most activities were in progress, with some activities completed and some not yet commenced. As noted in Section 8 of this report, it is anticipated that many PDP activities may be delayed by between 3-9 months due to the impact of COVID-19, with clinical trials particularly affected. However, as COVID-19 is still unfolding, it is a challenge to accurately predict the full extent of the impact of COVID-19 on activities. All PDPs have completed contingency planning and risk assessments, pivoted activities where possible and are providing regular updates on progress.

A few of FIND and MMV's activities have been delayed, deprioritised or cancelled, with clear reasons provided. The delayed activities *were* expected to be completed in 2020. It is noted that the product development processes, and portfolios of each PDP, are very different. Thus, Table 1 should be used to understand the progress of activities of each PDP but should not be used to compare progress between PDPs.

Table 1: Proportion of total contracted activities at different stages of progress in December 2019

	Completed	In progress	Not yet commenced	Delayed	Deprioritised	Cancelled
MMV	5%	79%	11%	0%	0%	5%
TBA	27%	73%	0%	0%	0%	0%
FIND	17%	37%	20%	7%	7%	12%
IVCC	57%	14%	29%	0%	0%	0%

DFAT is providing core funding to the PDPs, which enables the PDPs to maximise their efficiency by continuing to fund the most promising products for development and discontinuing development of those with limited added value. Under these conditions it is expected that some activities are cancelled, and that funding is pivoted to other activities.

Given the continued emergence of the impacts of COVID-19, it is possible that some activities may not be able to be completed within the funding period, or funding may need to be reallocated to activities that can be completed.

5.3 PROGRESS AGAINST KEY INDICATORS [EQ2]

The following section details the progress of the PDPs against indicators in DFAT's PDP Fund Monitoring, Evaluation and Learning Framework (MELF).

5.3.1 Product development pipeline [EQ6]

This review examined the number of products that each PDP had in their pipeline in 2018 and 2019 according to the stages as set out in the PDP Annual Funder Report template. For the purposes of this review, we aligned the pipeline stages with those in the template (see Annex 7).

In 2019, MMV had 13 products in their pipeline that were *complete,* TB Alliance 6, FIND 24 and IVCC 5 (Table 2). This is a strong indication of the progress of the PDPs in addressing unmet therapeutic, diagnostic and vector control needs in LMICs. Most of the PDPs have a significant number of products at the pre-clinical/feasibility stage – this is a normal pattern of distribution in a product development pipeline with more products at an early exploratory stage (see Figure 4). All PDPs have a significant number of products at the clinical trial and trialling stages, indicating potential for an imminent 'watershed' period of products coming to market as noted in the DNDi report cited later in this report.

Table 2 shows the total number of products at each stage of the pipeline in 2018 and 2019. It is noted that there is significant variation in the product development processes for therapeutics, diagnostics and VCTs and thus Table 2 should be used to understand the pipeline progress of each PDP and not to compare between PDPs. The complete stage is a cumulative total for all products developed since the launch of each PDP.

Table 2: Number of products at each stage of the pipeline by PDP and year

	Year	Pre-clinical/ feasibility	Clinical/pre-development - IVCC	Trialling	Complete (cumulative)
MMV	2018	19	10		13
	2019	20	13		13
TBA	2018	23	5		5
	2019	20	7		6
FIND	2018	25	11	20	23
	2019	16	9	22	24
IVCC	2018	>8	8	1	2
	2019	>8	5	4	5

5.3.2 Product access

Inclusion of new products in WHO guidance documents, such as WHO Standard Treatment Guidelines and the Model List of Essential Medicines is an important step in making them accessible. Countries look to WHO guidance in helping to determine whether products are safe and effective and to inform whether they are included in national guidelines and national lists of essential medicines. Inclusion of a product in WHO guidance documents is also a minimum standard for large scale product procurement for LMICs such as

through the Global Fund. During the funding period 2018-19, the PDPs report a steady stream of products that have been included in WHO guidance documents which indicates increased opportunity for product uptake.

During the same period, the PDPs report an increase in the number of products registered globally. This is another indication that products are progressing along the access pathway as registration by a Stringent Regulatory Authority (SRA) or National Regulatory Authority (NRA) must occur before a product is deemed safe and fit for purpose and can be placed on market. Table 3 below shows the number of products included in WHO guidance and registered in 2018-2019 by PDP.

Table 3: PDP product guidance and registration 2018-2019

	MMV		TBA		FIND		IVCC	
	2018	2019	2018	2019	2018	2019	2018	2019
Total number of products included per year in WHO guidance	3	1	1	1	3	2	4	0
Total number of products registered in one or more countries (cumulative)	10	11	1	2	15	16	4	5

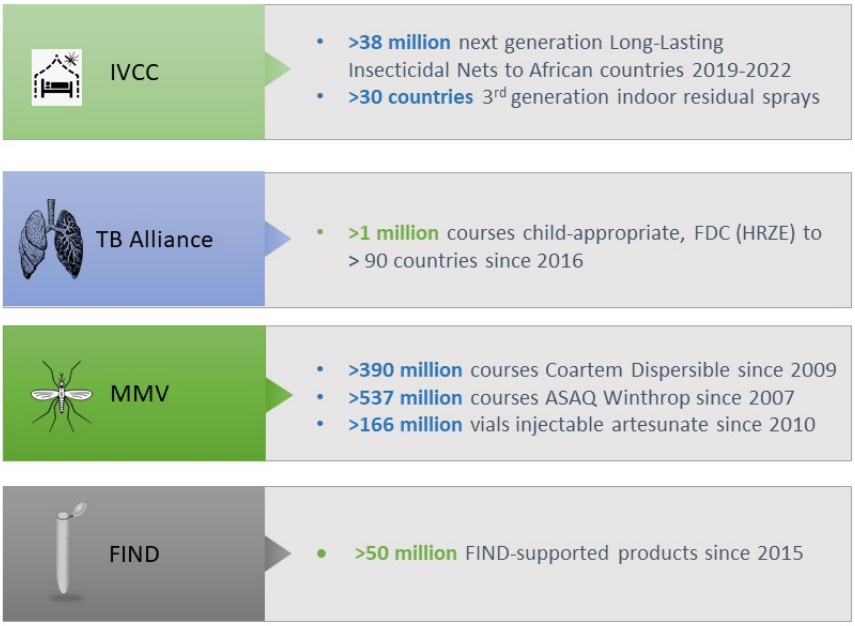
Product distribution

Another key measure of progress on the access pathway is their availability in the countries where they are needed. One way to measure this is in the number of products procured or distributed and the breadth of distribution. The PDPs provided examples of this, demonstrating significant distribution in multiple countries. This reporting however was sporadic, perhaps reflecting in part the difficulty accessing some of this data as the PDPs are not involved in distribution.

Other measures are needed to complement this further downstream on the access pathway. For example, measures could include the number of health workers trained in correct administration of the product and number of people treated with the product.

Examples of products distributed or procured as of 2019 are provided in Figure 3 below.

Figure 3: Examples of product distribution by PDP to Dec 2019



ASAQ Winthrop - artesunate-amodiaquine, fixed-dose ACT

SP+AQ - sulfadoxine-pyrimethamine [SP] + amodiaquine

Building country capacity and advocacy for product adoption

All four PDPs were involved in country-level advocacy or capacity building activities for the adoption of new products in the Indo-Pacific region. This building of capacity improves the long-term sustainability of product development and access ecosystem. Examples are given below.

MMV: The Regional MMV Advisor based in Thailand has been working with National Malaria Control Programs in the region to provide technical briefings on tafenoquine, including input into national policy briefings. MMV is working together with APLMA, who are presenting the larger advocacy case for improving the case management and radical cure of P. vivax (including introduction of tafenoquine) to governments. To date, this work has been carried out in Myanmar, Thailand, Cambodia, Vietnam and Laos.

TB Alliance: TB Alliance has aided PNG, Indonesia, Vietnam and Myanmar in their plans and protocols to introduce BPaL through operational research in 2020.

FIND: FIND has strengthened laboratory and/or testing site capacity in two locations each in PNG and Vietnam. It built capacity in mathematical modelling for policy by hosting a student from Vietnam in collaboration with the University of Oxford.

IVCC: IVCC has been advising Rotarians Against Malaria in upscaling indoor residual spraying (IRS) spraying in PNG. It also provided technical advice to WHO Vanuatu in developing a new IRS Strategy.

Note: The PDPs did not report on access activities and results systematically nor consistently, making it a challenge to monitor progress or build a business case for funding based upon achievements in access. It is acknowledged that much of this data may be held by other actors, such as product sponsors or regulators. This limitation was also noted in the DFID/PDPFG Preliminary Report.

5.3.3 Gender equality & disability inclusion [EQ7]

Gender equality

There was variation in the PDPs' reporting of their work in addressing gender equality. It is noted that there are some products for which it would be more relevant to explore gendered impacts than others. For example, around 125 million pregnancies are at risk of malaria each year, and up to 200,000 babies and 10,000 mothers die as a result, highlighting the importance of antimalarials that are safe to take during pregnancy.

MMV has a range of activities that are addressing the gendered impacts of malaria and their implications for treatment. It has developed a strategy for earlier testing suitability in pregnancy, which has been used in the development of two drug candidates. In 2019, it established the Malaria in Mothers and Babies (MiMBa) Initiative which aims to raise the standard of care for pregnant women and new-borns affected by malaria.

The other PDPs reported some or limited activities that addressed gender equality as part of maintaining good product development practice and required ethical conduct in research. This included compliance with ethics processes or trial inclusion criteria that considered gendered needs. FIND reported that it had 22 female staff based in LMIC leading research as principal investigators or equivalent in 2019 and have 45-55% female representation in senior management/governance roles. TB Alliance reported the female participation on community advisory boards for studies. IVCC reported little activity regarding gender equality and is currently engaging with gender advisors and DFAT to identify ways to strengthen this. All PDPs have a gender, equality and/or diversity policy or equivalent.

The PDPs have projects that aim to ensure equal access to gender-responsive health services and health education, particularly for women caregivers and community healthcare workers. For example, FIND is involved in activities to empower women to access rapid TB diagnostics in marginalised rural communities in India. All the PDPs disaggregate their study data by gender (including IVCC's epidemiological trials) and have undertaken relevant studies, with examples given below.

- TB Alliance: Results from the KNCV LSHTM BPaL studies that highlight the impact BPaL will have on all vulnerable populations including women (2019)
- MMV: Phase IV study evaluating the cardiac safety of DHA-PQP for use as a potential new tool for intermittent preventive treatment of *P.falciparum* malaria infection in pregnant women in Tanzania (2016 - ongoing)
- FIND: The use of hsRDT (highly sensitive rapid diagnostic test) versus a conventional RDT for the detection of *P. falciparum* infections in pregnant women in PNG and Benin (2019)
- IVCC: The Potential Impact of Eradicating Malaria on Gender Inequality within Agricultural Households in sub-Saharan Africa – including discussion of how a reduction in gender inequalities in households could impact the effectiveness of vector control interventions (2020).

There is potentially more that could be done by the PDPs, including addressing equitable access to capacity strengthening activities, reducing barriers to product access for women and, where appropriate, identifying potential studies or market analysis activities looking at gendered impacts of diagnosis, prevention and treatment of the products being developed.

Disability inclusion

The PDPs have equality and diversity strategies or equivalent which include people living with a disability. For example, the IVCC adheres to the Liverpool School of Tropical Medicine's Equality and Diversity Strategy. Some good practice guides including on disability have been developed to aid implementation of the strategy.

Apart from a general statement by TB Alliance that it conducts research that considers vulnerable populations including patients with disabilities, there were no specific activities that were reported by the PDPs that addressed disability inclusion. It would be useful to have a disability inclusion expert examine the work of the PDPs and identify areas of potential strengthening.

5.4 EFFICIENCY & VALUE FOR MONEY

5.4.1 Efficiency

The performance of the PDPs is monitored by the PDPFG and the PDPs submit reports on activities using a standard template and metrics as well as financial reporting. MMV, TBA and IVCC reported small variances of between 3% to -9% between their organisational budget forecasts and their actual expenditure in 2018 and 2019, demonstrating sound budgeting processes and an indication of an efficient use of funds (Table 4). In 2018, FIND reported a 28% overspend, attributed to an unexpected no-cost extension to a large TB grant.

DFAT provides core funding to the PDPs, and as such, detailed input into the financial management of their activities is not warranted. However, despite the nature of this funding, during 2018-19 IVCC and FIND also provided acquittals for DFAT funds. In these reports, FIND reported a significant underspend of DFAT funds in the first six months of the funding period to Dec 18 (variance -40%) and an underspend of 14% by the end of 2019. The underspend in 2018 was attributed to less expenditure than expected for the TB program and a de-prioritisation of the AMR project, with funds being reallocated to other activities in 2019. IVCC also reported a significant underspend of -84% in its first reporting period (FY18-19). This underspend reflects delays in the start-up phase as IVCC worked to complete their landscape mapping activities and delays in finalising partnerships contracts, all of which were subsequently finalised in late 2019 and early 2020.

Table 4: PDP organisational budget, expenditure and variance by year

	2018			2019		
	Budget	Expenditure	Variance	Budget	Expenditure	Variance
MMV (USD)	$87,000,000	$84,500,000	-3%	$100,800,000	$96,600,000	-4%
TBA (USD)	$61,425,000	$60,315,645	-2%	$70,622,000	$69,535,079	-2%
FIND (USD)	$46,673,000	$59,564,000	28%	$61,156,238	$56,266,482	-8%
IVCC* (GBP)	£36,288,000	£37,290,000	3%	£39,427,000	£35,980,000~	-9%

* FY 18/19 and 19/20 ~ Anticipated consolidated expenditure only (year end 31 Jul 20)

It is noted that this Mid-Term Review was not tasked to provide a full financial assessment of the PDPs.

For further discussion on the efficiencies gained by the PDPs collaborating with Australian institutions, other HSI-funded programs and partners in the region, see Section 6.

5.4.2 Value for money

The PDP model has been presented as an approach which represents good value for money for a number of reasons including that it: i) Pools public and private funds and in-kind contributions to be able to address market failure by developing products for diseases affecting LMICs that could/would not be developed by governments or private sector entities ii)Takes a collaborative approach, leveraging the comparative advantage of different actors along the product development and access continuum iii) Reduces risk by cost sharing between public and private sector actors iv) Utilises a portfolio approach to development with the ability to drop unpromising product candidates, fast-track promising research, explore combination therapies and to be responsive to country needs and R&D opportunities v) Develops products on a not-for-profit basis at a fraction of the cost of private sector product development. For example, MMV estimates its average drug development cost is USD$4.5M per year compared to USD$12.5-25M for industry. In the DFID/PDPFG Preliminary Report, TB Alliance estimated the total development cost for pretomanid to be about 10% of the high-end cost estimate for new product development by the pharmaceutical industry.

The DFID/PDPFG Preliminary Report found that the assumption that the PDP model is cost effective as compared to other R&D models still holds. However, it noted that a thorough analysis of the entire value chain of PDPs is needed, including in-kind costs and the contribution of partnerships and that this could then form the basis of a robust comparison against other R&D models.

An analysis of the Australian investment in activities of the four PDPs found that for every US$1 invested by Australia, MMV has an investment impact of US$3.50, TB Alliance US$1.68 and FIND US$4. Moreover, DFAT's collaboration with the PDPs has enabled it to develop synergies between the work of the PDPs and other investments. This amplifies the impact that DFAT funds can have in supporting progress along the product development to access continuum. Furthermore, over the course of this and previous investments in PDPs, the formal partnerships and collaborations between PDPs and Australian institutions have resulted in mutual benefits. *See Section 6 on PDP partnerships and collaborations.*

The PDPs have generated evidence to demonstrate the large-scale health and economic impacts of their work. For example, MMV estimates that it has generated USD 28.5 billion in economic benefits by saving over 2.2 million lives. BPaL, developed by TB Alliance, generally reduces the cost of treatment by 40-50% and a McKinsey investment case study estimated that the rapid introduction of BPaL could translate to a savings for health systems of US$0.7-1.1 billion to 2023.

5.5 RISK MANAGEMENT [EQ6]

The most significant risk facing PDPs at the time of this report was both the shorter and longer-term impacts of the COVID-19 pandemic. These are discussed in Section 8 below.

The PDPs regularly identify, monitor and report on risks. Four of the common risks identified across the PDPs are discussed below.

1. Potential reduction in funds – this is a perennial risk for the PDPs, exacerbated recently by the focus of funding for the COVID-19 response and the growing global economic downturn which may impact on the levels of donor government support. In addition, product development requires long-term investment, while funding commitments are often interlinked with political cycles that tend to be shorter-term.

The high reliance on a few funders also poses a risk. In 2019, BMGF was the largest funder of MMV and TBA, the second largest funder of IVCC and fourth largest of FIND. DFID/UKAID (now the UK Foreign, Commonwealth & Development Office)/Secretariat of State for Health was the largest funder of FIND and the second-largest funder of MMV and TB Alliance. Despite the launch of its Medical Research Institute (MRI), BMGF is committed to continuing funding of all PDPs at a similar level and has recently renewed its multi-year funding to MMV and IVCC. BMGF interviewees for this report noted that there will be a slight

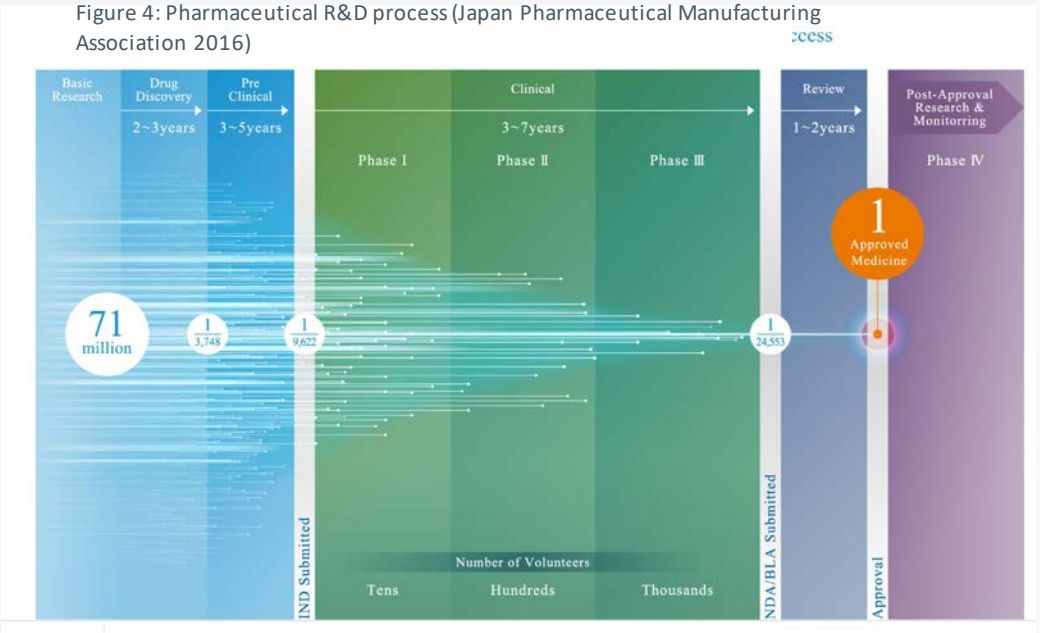
decrease in funding to TB Alliance, as the MRI picks up some of product development work in TB. The DFID/PDP FG Preliminary Report called for longer-term end-to-end product development funding and a TB Alliance interviewee called for longer-term strategy-level funding commensurate with product development timeframes. PDPs are exploring alternative funding mechanisms, such as FIND's exploration of loan structures with the European Investment Bank and MMV's establishment of the Foundation Fund in 2019 to invest extraordinary revenue (such as from the GSK Krintafel partnership) in order to improve business sustainability.

2. Move away from core funding - an important element of the PDP model that was noted by some of the PDP and funder interviewees was the use of core funding, which enables PDPs to have the necessary flexibility to manage their pipelines efficiently. However, some donors have been drifting away from portfolio funding in favour of individual project funding, a trend noted by some of the PDPs and funders interviewed, as well as acknowledged in a recent access report for the PDPFG and in PDP risk management reporting.[3] Measures that MMV is taking to mitigate this risk include developing funding proposals around areas such as *P. vivax* and elimination rather than focusing on products, and including back-up products in proposals.

3. Declining role of pharmaceutical industry in late stage discovery and in access – A number of PDP representatives as well as the private sector interviewees noted an increasing role for the PDPs in activities to ensure product access, and a simultaneous decline in access work by the pharmaceutical sector. *See Section 9.3 Opportunities and Challenges for Product Access below.* This trend will require changes in PDP capacity and capability, new collaborations and consideration of end-to-end donor funding.

4. Inherent risk of product development – product development has always been an inherently risky process, due to the large number of compounds and candidates that need to be explored to identify an effective product, and the associated long timeframes and high costs involved (Figure 4). PDP donors share these risks and the PDP portfolio approach enables agile product development processes whereby promising candidates are pursued and candidates with insufficient added value are dropped.

Figure 4: Pharmaceutical R&D process (Japan Pharmaceutical Manufacturing Association 2016)



5.6 SUSTAINABILITY [EQ6]

There are several ways that the PDPs are moving to support the sustainable uptake of their products as well as their own long-term viability in product development. Several are discussed in other sections of this report and are briefly listed here:

[3] McNeil M (2018). No success without access: Perspectives from funders, PDPs and international agencies on challenges and opportunities around access to new products developed by PDPs (Draft), February.

Sustainable development and uptake of products

- PDPs are increasing their own work and partnering with other entities in product access, including in strengthening country capacity in health technology assessment and in product distribution and use, as well as establishing models and programs for equitable product access.
- There has been an increasing focus on Target Product Profiles s and market analysis to ensure that the product development process reflects country needs and capacity.
- The PDPs are investing in building partner country capacity in laboratories, conducting clinical trials and in other research areas to ensure the quality and sustainability of research results and product impact.
- The PDPs have diversified manufacturers of their products, including introducing generic competition, and are working with global procurement and distribution mechanisms such as the Global Fund to ensure a sustainable and affordable global supply of their products.
- The PDPS are working with partners to improve forecasts for product demand by countries to ensure a sustainable product supply. Accurate and timely forecasting remains a challenge, highlighted in the DFID/PDP FG study.

Sustainability of the PDPs

- Some PDPs are exploring the diversification of their funding streams by looking at alternative funding mechanisms and sources (such as US FDA Priority Review Vouchers – granted to sponsors of tropical disease product applications) as well as through collaborations with newer product development partners such as GHIT or the RIGHT Fund.
- The DFID/PDP FG Report and some PDPs interviewed proposed moving to longer term strategic funding of product development, with timeframes such as 10 years which correlate better with product development timeframes.
- COVID-19 may cause a longer-term diversion of funds away from PDPs or may reinvigorate their funding due to an increased awareness of the importance of global health R&D and the impacts of the pandemic on the progress against diseases such as TB and malaria. The global economic downturn will likely have an impact on donor funding.
- The PDPs continue to maintain and diversify their partnerships to leverage technical and geographical expertise as well as financial and in-kind resources.

See also Section 5.5 on risk management.

5.7 LESSONS LEARNT

The following are some key lessons learnt that have been identified by the PDPs and their industry partners in implementing and managing their work.

- FIND: There is a need to develop cross-functional skill sets within the organisation – to break down the silos of development, increase capacity for timely mitigation of risks and increase efficiency.
- FIND: There is a need to find a balance between innovation and solutions that can be implemented in countries. For example, while there is strong potential in the use of electronic decision tools – dedicated algorithms i.e. AI and machine learning - to help guide care and surveillance, governments may have little appetite to implement such tools outside of research. There may also be limited local guidance, regulations or capacity to use such tools.
- FIND: There is an increasing interest to expand integration of health services at a community level, including from partners in Southeast Asia and the Pacific. The challenge is that FIND has traditionally

worked on diagnostic tests at primary health care level. Working with community health providers will require a shift in FIND's expertise towards implementation guidance provision.

- FIND: While working with national or state programs on access, data access and transparency is key if projects are intended to influence national or regional policy. Therefore, even if the state program has a solid data capture system, additional quality assurance measures should be undertaken by the PDP to ensure robust data for advocacy.
- IVCC: It is important to ensure that product prototypes are fit for scale up in large scale testing before launching a trial plan.
- MMV: Joint communication and advocacy with other PDPs and advocacy groups in the field of malaria and neglected diseases allows for great visibility.

During this review, CHS PDP Fund Program Managers also reflected upon the lessons learnt. They identified the mutual value in the CHS being engaged with the PDPs at different levels, including on the CEPI Investors Council, the IVCC Board level and Indo Pacific Initiative's Advisory Group (as an observer) or in brokering relationships and sharing information between PDPs and other relevant actors and HSI-funded programs. The CHS staff acknowledged that they at times had limited capacity to be able to play a relationships-brokering role and that many Australian Posts also have limited capacity for such work. Finally, this review identified the challenge in monitoring the progress of the PDPs, given the different reporting formats used by the PDPs, the varied quality of reporting in the PDP Funder Template and the different types of the product development processes used. It found the DFID PDP Results Reporting Template completed by some PDPs useful and undertook a process to harmonise reporting of pipeline which is used in this report. However, it is acknowledged that the PDPs have a significant reporting burden and there is a continued need to streamline and pool reporting requirements.

5.8 RELEVANCE

The PDP Investment Design describes the objective of the PDP Fund as being *to accelerate access to new and effective tools to contribute towards reduced disease burden in the Indo-Pacific.* The end of program outcome (EOPO) in the program logic (which has been updated as part of this review – see Annex 4) is for *Increased access to, and use of, new or modified medicines, vaccines, diagnostics and vector control tools in the Indo-Pacific in order to manage infectious disease threats.* This review has found that the PDPs have demonstrated progress towards this EOPO, as evidenced in their development pipelines, WHO endorsements and registrations of products and in the distribution of their products. These correlate with interim steps along the program logic. The PDP Investment Design also included an approach which would seek coordination with other HSI investments, to contribute to accelerated product development and uptake. This built upon a recommendation in the 2017 evaluation of the previous phase and has occurred through the work of the RSP, APLMA and some of the operational research work with HSI partners. It could continue to be strengthened for the remainder of the funding period.

The evaluation of DFAT's 2013-2018 investment in PDPs recommended that vector control was added to DFAT's funding of diagnostics and medicines. This was actioned in the funding of IVCC, and its projects are already beginning to integrate with other HSI-funded programs. The evaluation also recommended that DFAT play a more proactive and engaged role in the PDPFG. This has been the case as Australia has taken on the role of one of the rotating chairs of the group and in another role, DFAT has played an active role on CEPI's Investors Council.

This review has found a high degree of fidelity between the initial design and the activity to date, and that the investment design remains fit for purpose. There is also evidence that several of the recommendations in the evaluation of the 2013-2018 investment have been actioned and resulted in improvements to the management of the PDP Fund, and engagement with PDPs and others in the PDP ecosystem.

6. PDP PARTNERSHIPS AND COLLABORATIONS IN THE INDO-PACIFIC

This section describes the partnerships and collaborations of the PDPs in the Indo-Pacific region. Partnerships are defined in this report as agreements to work on something together that will benefit all involved, generating results that could not be achieved by a single partner alone and reducing duplication.[4] Collaborations are less formalised arrangements to work together.

6.1.1 Australian Institutions

PDPs have developed significant partnerships and formal collaborations with many Australian institutions, including with research institutions, universities, reference laboratories and advocacy groups. Within the scope of their DFAT-funded work, MMV has at least nine formal working relationships with Australian institutions, TB Alliance six, FIND eight and IVCC four. The PDPs also have other Australian partnerships linked to work supported by other funders.

Key institutions that have relationships with more than one PDP include:

- The Burnet Institute (FIND, TB Alliance, IVCC, MMV)
- Walter and Eliza Hall Institute (MMV, FIND)
- Australian Defence Force Malaria and Infectious Disease Institute (MMV, IVCC)
- QIMR Berghofer Medical Research Institute (MMV, IVCC)
- Monash University (TBA, MMV).

The Burnet Institute has a particularly strategic role as it is collaborating with all the PDPs. As the PDPs have limited or no presence in the region, they rely on partners such as Burnet as a trusted partner for information about the local context, to act as a relationship broker with local organisations and to undertake high calibre, country-based research. FIND reported that they are currently exploring whether they can partner with Burnet in building a regional research platform. Burnet's strengths in the above areas have enabled the PDPs to make inroads and establish research projects in the region. Burnet is working on other HSI-funded programs: STRIVE, STRATUM, PRIME-TB. Burnet has established internal structures to coordinate among their health security and PNG programs. CHS needs to ensure good communication and coordination between all HSI-funded programs involving Burnet and should continue to identify and support, together with Post, points of leverage or synergy across these programs. This could be strengthened through periodic discussions with focal points at Burnet who coordinate activities across these programs.

In some instances, DFAT has been instrumental in brokering working relationships. For example, DFAT awarded a grant to the Peter Doherty Institute for Infection and Immunity (Doherty Institute) to enable COVID diagnostics in the Solomon Islands, PNG and Fiji. FIND and the Doherty Institute are now exploring areas of collaboration, including tools for lab strengthening, training and data collection and management in the region. DFAT has facilitated these discussions and provided insights to FIND on the objectives of the grant to the Doherty Institute.

The feedback from PDPs and other stakeholders has been that the partnerships with Australian institutions have been mutually beneficial. The PDPs have benefited from the technical know-how and networks of the Australian partners, while at the same time the PDPs bring an output/impact-oriented focus which can assist Australian teams to translate their academic or technical expertise into long-term, practical impacts.

[4] OECD, Successful Partnerships – a guide, OECD LEED Forum for Partnerships and Local Governance. Available at: www.oecd.org/cfe/leed/forum/partnerships

6.1.2 PDP Partnerships in the Indo-Pacific

The PDPs have developed a significant network of partners across the Indo-Pacific. The partners include research institutions, universities, hospitals, ministries of health, NGOs, advocacy groups and the private sector. MMV has at least 23 formal working relationships with actors in the Indo-Pacific, TB Alliance 19, FIND 16 and IVCC eight.

Key institutions that have or will have relationships with more than one PDP include:

- PNG Institute of Medical Research - PNGIMR (IVCC, FIND)
- Mahidol Oxford Research Unit Thailand (FIND, MMV)
- APLMA/APMEN (MMV, IVCC, FIND)
- Newcrest Mining (MMV, IVCC – through NATNAT partners).

The PDPS are also working on projects with other product development entities. For example, GHIT is working with MMV and TB Alliance and the Korean RIGHT Fund is working with MMV and FIND.

6.1.3 Links between PDPs and other HSI-funded programs

There is a complex array of both formal and ad hoc collaborations and communication channels between the PDPs and other HSI-funded investments. Most of the collaboration is with the Regulatory Strengthening Program (RSP), APLMA and the HSI-funded operational research projects. These types of collaborations have: supported the progress of product development and uptake, usually of specific products; created an enabling environment in which product development can take place; and/or strengthened capacity through the sharing of technical or regionally specific knowledge and expertise. These collaborations have had demonstrable mutual benefits to both the PDPs and the HSI-funded programs.

Some examples of these benefits include:

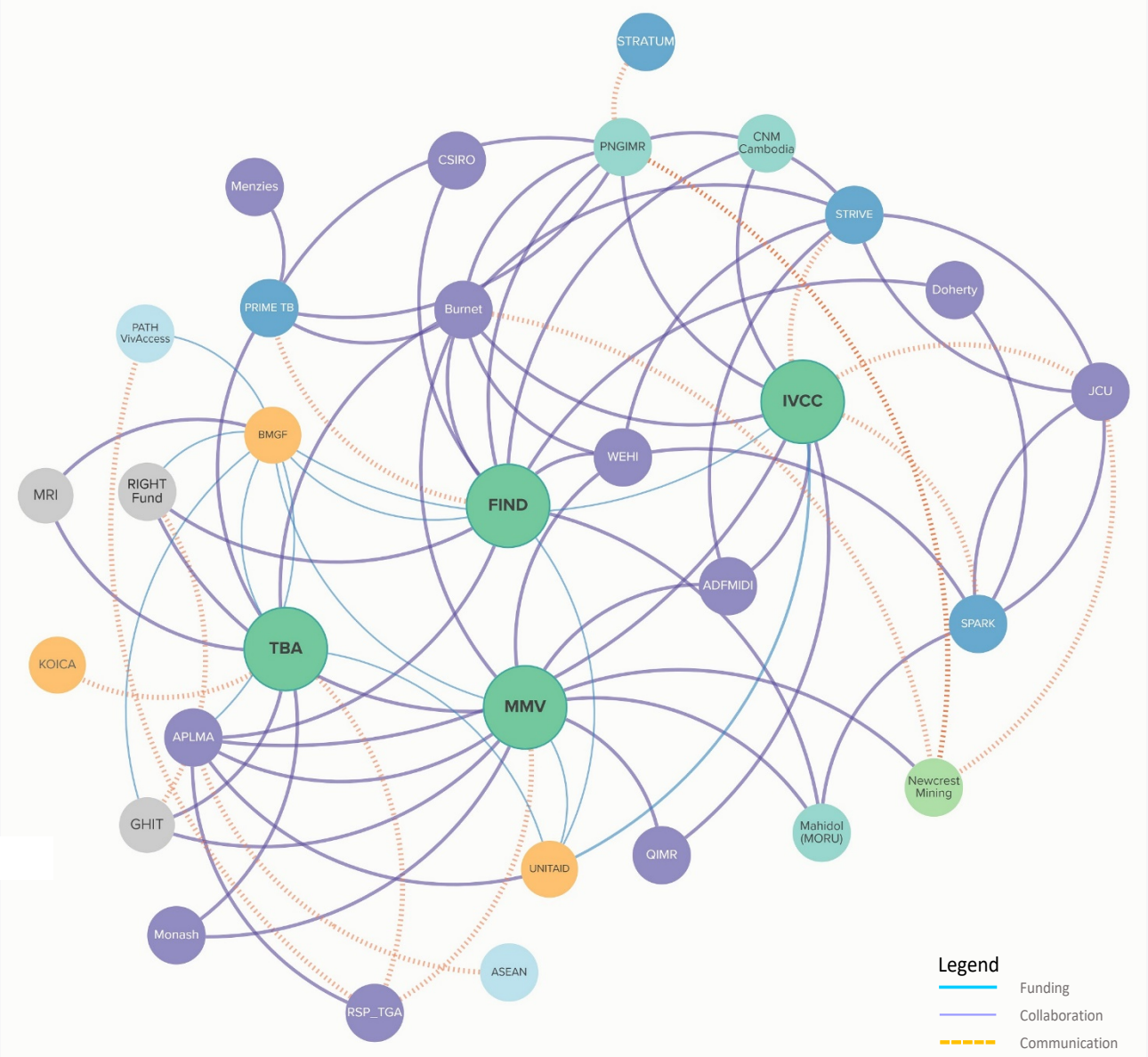
- **RSP/MMV(GSK):** A newly established reliance pathway between Thai FDA and TGA enabled TGA assessment reports for tafenoquine to be shared with Thai FDA (with GSK approval) and product approval in 109 working days instead of the average 220 working days (Apr 20)
- **APLMA/IVCC:** IVCC landscaping reports funded by HSI were launched at a regulatory meeting of the Vector Control Platform for Asia Pacific (VCAP – an initiative developed by APLMA/UNITAID) (2019)
- **RSP/TB Alliance/Mylan:** TB Alliance/Mylan presented their roll-out plans for BPaL at the RSP Forum (Sept 19)
- **Burnet/IVCC:** There is good on the ground collaboration between NATNAT (IVCC project led by Burnet), STRIVE (another HSI-funded program run by Burnet) and Post-funded malaria work in PNG.

> Linking MMV to RSP has been a huge win…to help prioritise some of the regulatory functions that need strengthening. One of the requests from MMV was a need to strengthen pharmacovigilance. This request was passed forward to RSP. RSP through their consultations with regulators made this part of the country work plans. This is a really good example of alignment of all the DFAT investments and getting all the relevant stakeholders on board.
>
> - APLMA

See Annex 8 for a more detailed table of the collaborations between the PDPs and other HSI-funded programs.

6.1.4 Product Development Ecosystem in the Indo-Pacific

The following stakeholder map depicts the connections between PDPs, other HSI-investments and other actors involved in product development and access in the Indo-Pacific. It shows only those actors with multiple connections to others and thus is a selective picture of the product development ecosystem in the region. The diagram distinguishes between the types of connections among actors, delineating between formal partnerships/collaborations, communication (but no partnership) and funding relationships. See Annex 9 for filtered ecosystem maps for each PDP.



7. DFAT'S SUPPPORT AND ENGAGEMENT

7.1.1 DFAT Support

The PDPs universally expressed their appreciation for their positive working relationships with CHS staff and identified three main areas where their collaborations with CHS staff have been able to add value:

1. **Relationship brokering –** the PDPs have relied on CHS and their partners to help to expand their networks in the Indo-Pacific, particularly in support of their operational research as well as product registration. For example, CHS introduced IVCC to the SPARK program and there is now regular communication and collaboration to ensure the work to the two programs align. *See also 6.1.1 for the example with the Doherty Institute and FIND.*
2. **Contextual knowledge –** CHS Program Managers have provided the PDPs with relevant regional updates and knowledge, such as providing TB Alliance with information about the processes for the development of PNG's new National TB Strategic Plan and their Global Fund grant. They have also connected PDPs with HSI partners that have also been able to provide this knowledge, such as Burnet's country specific knowledge and networks or TGA's knowledge of national regulatory processes.
3. **Strategic input and leadership –** CHS Head Robin Davies has represented Australia on PDPFG meetings and has been the chair on a rotating basis. A number of interviewees for this review noted the technical and leadership strength he brings to the group. They also noted the value of the PDPFG more generally as an important informal mechanism for funders to share and learn from each other and to coordinate activities. Some interviewees did note that coordination, including of donor-funded activities at a country level, could be further strengthened. Robin has also represented Australia on CEPI's Investors Council and has made a number of strategic inputs to this group that have been taken up.

> Engagement from DFAT is very, very positive. I think that the engagement and interaction we have with them is well balanced.
> They [CHS] are very integrated and supportive, it's much more of a partnership than a funder.
>
> - IVCC

The above are important additions to the role that CHS staff must play in managing and administering the PDP investments. The examples demonstrate how this work has a reciprocal but often 'unseen' benefit to both the work of the PDPs and the other HSI investments. The PDPs were able to point to several additional areas that CHS staff could support should they have the capacity. CHS staff acknowledged that they were at times limited in their capacity to be able to respond to areas of support that they identified, such as in liaison between Post, the PDPs and other HSI investments.

CHS staff are able to play these roles because of the Centre's networks and strong relationships within the Indo-Pacific, the staff's strong knowledge of both the Indo-Pacific regional R&D context as well as the R&D process and their capacity to lead and work strategically. It will be important going forward to ensure that there is sufficient capacity and expertise among the CHS staff to maintain these roles, as well as strong knowledge management to enable continuity of the relationship and knowledge brokering work and the integrity of CHS inputs.

> This triangular flow of information has worked very well on DFAT's PIDP Grant to the Peter Doherty Institute and could extend to other grants that DFAT awards to Australian institutions.
>
> - FIND

7.1.2 Potential Areas for Australian Government PDP Support and Engagement [EQ5]

Through the document review and the interviews, ways in which CHS staff could either maintain or strengthen their roles in supporting the PDPs, and product development and uptake more generally within the current funding period were identified. Suggested key areas are described below.

Information sharing and relationship brokering

- Continuing to provide updates to PDPs on contextually relevant information in the Indo-Pacific and making opportunistic links to increase communication and collaboration where relevant with other HSI-funded programs and with others in DFAT networks.
- Continuing to facilitate linkages and collaborations between PDPs and relevant Australian institutions, other Australian Government departments, Posts and funding opportunities e.g. MRFF.
- Supporting relevant engagement between the PDPs and SEARO and WPRO, noting the latter's capacity limitations.

Product Development and Access

- Supporting the establishment of operational research in the region, including through Posts.
- Continuing support for addressing access barriers for PDP products in the Indo-Pacific region, in coordinating with other actors including those in Japan and Korea through regular communication.
- Encouraging new or increased funding and engagement in product development by MICs in the region such as Thailand and Malaysia.

Product Regulation

- Increasing information-sharing about the work of the RSP, supporting communication links between TGA and the PDPs on registration processes in Australia (FIND, TBA) and coordinating and sharing information with PDPs on relevant work in RSP partner countries. In addition, providing updates to TGA about the work of PDPs, including plans to present data packages to NRAs. Continuing to support the strengthening of joint registration processes in the Indo-Pacific through the RSP.

Health Diplomacy

- Health diplomacy in order to ensure continued donor and other support for combatting TB, malaria and other diseases particularly given the risk of funding diversion/reduction due to COVID-19 and the significant long-term impacts of the pandemic on the progress against these diseases. This could include Australian Government representation to other partner governments by CHS staff working together with Australian Posts as well as representation through global and regional forums.
- Health diplomacy at clearly identified strategic points in support of APLMA's policy work and the activities of VCAP e.g. with policy makers/ASEAN to improve the regulatory environment for VCTs.

Coordination with other Australian Government Investments

- Increasing the efficiency and 'end-to-end' impact of related Australian Government investments through strengthened coordination and communication among government departments. This would currently involve the following investments: RSP, PDPs, APLMA, Global Fund, operational research programs, International Financing Facility for Immunisation (IFFIm), World Bank and Gavi, the Vaccine Alliance. This could involve sharing of intelligence across investments, coordination of related activities along the continuum and close communication where there are shared partners and networks.

8. COVID-19 IMPACTS AND RESPONSE

This section describes three dimensions of PDP activities in relation to Covid19: DFAT funding of the COVID-19 vaccine response, the roles of the PDPs in the COVID-19 response and the impact of the pandemic.

8.1.1 Funding the PDP COVID-19 vaccine response

The Coalition for Epidemic Preparedness (CEPI) is a global partnership launched in 2017 to develop vaccines to stop future epidemics. The Access to COVID-19 Tools (ACT) Accelerator is a WHO-led global collaboration for the development, production and equitable distribution of vaccines, therapeutics and diagnostics for COVID-19. In March 2020, CEPI was designated co-lead organisation for the vaccines pillar of the ACT Accelerator – COVAX – which was launched in partnership with WHO and Gavi. The goal of COVAX is to provide an end-to-end solution to develop, manufacture and equitably deliver up to two billion doses of vaccine by the end of 2021.

In November 2019, DFAT committed AUD$4.5million to support CEPI's core work for three years to December 2022. In May 2020 at the Global Coronavirus Response Summit, Australia announced a further AUD$7.5million towards CEPI's development and manufacture of a COVID-19 vaccine. DFAT is a member of CEPI's Investors Council and has observer status for CEPI Board meetings. CHS Head Robin Davies engages regularly in these meetings and there is evidence that his strategic advice to the Investors Council has been well received and actioned.

At the end of July 2020, COVAX was supporting nine promising vaccine candidates, with seven already in clinical trials. Globally there were more than 200 COVID-19 vaccine candidates, with 22 in clinical trials. One of the seven COVAX-supported candidates is being developed by the University of Queensland (UQ). In January 2020, CEPI allocated US$4.5million to UQ to advance development of the vaccine candidate, which has also been supported by AUD$5million in Australian Government funding. In June 2020, a partnership agreement was signed between CEPI, UQ and Australian manufacturer CSL to fund clinical development and industrial-scale manufacture of the vaccine. The Doherty Institute, CSIRO and others have also been involved in developing the vaccine. In July 2020, the first patients were enrolled in the Phase 1 clinical trial and preliminary results were expected by the end of September 2020.

8.1.2 PDPs' role in the COVID-19 response

The PDPs have been playing a significant and active role in several areas of the COVID-19 response and in mitigating the impacts of the pandemic on the progress against other diseases.

FIND is co-leading the ACT-Accelerator's Diagnostics Pillar with the Global Fund and in early July 2020, FIND and UNITAID called for proposals to accelerate the availability and manufacturing scale-up of rapid diagnostic tests for COVID-19. FIND's Pandemic Preparedness Programme, set up internally in late 2019 to respond to COVID-19, has supported capacity building for African public health labs, materials to support assay validation, proficiency testing and quality assurance, and independent evaluations of molecular assays. FIND is operating a dual structure, with its Pandemic Preparedness Programme and another arm maintaining core business. Concerns had been raised by a few donors about FIND's capacity to support both areas of work. CHS has been representing Australia on FIND's Donor Council for the Diagnostics Pillar of the ACT-Accelerator. The Donor Council provides guidance to FIND on the management, oversight and potential funding of its ACT-Accelerator activities.

MMV has been co-lead for the WHO Supply and Commodity Workstream for the malaria COVID-19 response. Among other activities, it has also been involved in clinical trials for COVID-19 involving anti-malarials, shipping pandemic response box sets containing antivirals to researchers and conducting

modelling and simulations on the predisposition of some of these drugs in the lungs. MMV noted that members of its leadership team have also been contributing their expertise to various high-level working groups on the COVID-19 response but that it was a challenge to financially resource this type of work.

TB Alliance is working with research partners on a proteasome inhibitor that may have therapeutic value against coronaviruses. IVCC has been tracking and regularly reporting on the impact of COVID-19 on upstream supply with IRS and Long Lasting Insecticidal Net (LLIN) manufacturers on behalf of the task force being led by the Alliance for Malaria Prevention. It has also been reporting on the impact of COVID-19 on its portfolio as well as on its partners and related contract research organisations.

The DFID/PDP Funders Group Preliminary Report pointed to potential positive consequences for all PDPs arising out of the COVID-19 response, including improved speed and level of international collaboration in global health R&D; the longer-term opportunity to rally R&D support for other diseases due to greater awareness of R&D needs; and an increase in the sharing of scientific knowledge.

8.1.3 COVID-19's impact on PDP activities

All PDPs report that COVID-19 has and will continue to have an impact upon their activities. The impacts are wide-ranging, from the inability to run clinical trials due to travel restrictions and overwhelmed health systems, supply disruptions due to diversion of manufacturers to COVID-19 related products or restrictions on freight movements, and diversion of technical expertise to COVID-19 efforts. The PDPs estimate short-medium term delays in some activities of between three and nine months, particularly in clinical trials. It is noted that TB Alliance said that they were able to complete recruitment for their Zenix and SimpliciTB trials pre-COVID19, and so these trials are continuing on schedule. However, at the time of writing, all predicted that they would be able to complete the DFAT-funded activities by the end of the funding period in 2023. The final extent of the impact of COVID-19 on PDP activities is unknown.

There are also likely to be longer term impacts of COVID-19 on the work of PDPs including the diversion of resources towards R&D for COVID-19, lack of appetite and capacity of countries to approve and roll-out new (non-COVID-19 related) products, a regression in the gains made in combatting diseases targeted by PDPs, and a reduced ability of governments to financially support the PDPs due to the global economic downturn.

All PDPs have taken a rapid and proactive approach to pivoting activities as a result of the impact of COVID-19 and have been managing the associated risks. For example, MMV have taken steps to safeguard access to critical anti-malarial medicines and critical malaria campaigns. FIND have prioritised remote or desk-top activities, brought study analyses forward and initially tried to work with manufacturers and populations not in lock down. FIND have a two-week cycle of risk monitoring and they report to their Audit and Finance Committee on programmatic and financial risks every two months. IVCC have undertaken scenario planning to look at options for completing activities to schedule. All PDPs are regularly updating donors and proactively managing associated risks.

9. FUTURE DIRECTIONS IN PRODUCT DEVELOPMENT AND ACCESS [EQ8]

The following section provides a summary of the key trends and future challenges in product development and access identified through the document review and interviews for this Mid-Term Review. A more detailed description of these key trends and challenges can be found in Annex 10. This analysis focused on developments that are most relevant to the work of DFAT as well as those in Southeast Asia and the Pacific.

Future Directions in Product Development and Access: Key Takeaways

1. It is anticipated that there will be a 'watershed period' in PDP development in the next five years, with the anticipated completion of many new products.
2. The ACT-Accelerator will provide valuable lessons on the organisation and collaboration of different components of the product development and access ecosystem for the rapid roll out of new products.
3. There are several recent models for product development, including the MRI, GHIT, CEPI and the RIGHT Fund. The PDPs are collaborating on projects funded by these models, which add to, rather than detract from, the product development ecosystem.
4. There is an increased blurring of the boundaries between those actors involved in product development and those involved in access, with PDPs playing a greater role in the access space while pharmaceutical companies are reducing their role. PDPs need to build capacity and capability to fulfil this growing 'end to end' role and continue to strengthen partnerships in access.
5. There have been several workshops and papers on addressing access bottlenecks, and the appetite is now for action. There is a recognition that this requires mechanisms for governance and decision making, which are currently lacking. One potential mechanism for this currently being scoped by Wellcome is the Annual Global Forum.
6. There is widespread interest among interviewees for a critical path approach for access i.e. mapping the access pathway for a product and then leveraging the areas of comparative advantage of different actors to facilitate progress along this pathway.
7. There are regional initiatives to improve product access including the Access and Delivery Partnership (ADP) (UNDP, WHO, TDR and PATH) and the Uniting Efforts initiative (Government of Japan, UNDP – lead, GHIT). Uniting Efforts, if expanded, could be an important mechanism for coordinating regional access efforts.
8. There are many areas of synergy and partners in common in the work of KOICA, GHIT, the ADP, Uniting Efforts and DFAT in product development and access in Southeast Asia and the Pacific. There is little interaction between DFAT and these entities at present. Efficiencies could be gained by opening up better lines of communication with relevant actors, particularly those working in regulatory strengthening in the region.

10. CONCLUSIONS [EQ3]

The following conclusions related to the retrospective part of this report and the progress and support of the four HSI-funded PDPs (MMV, FIND, TB Alliance and IVCC) except for the section on COVID-19.

PDP Progress (MMV, TB Alliance, FIND, IVCC)

1. **Key achievements:** All PDPs reported achieving significant product development milestones during the funding period. The regulatory approval of tafenoquine (MMV), pretomanid as part of the BPaL regimen (TB Alliance) and the Malaria-LAMP and SILVAMP TB LAM tests (FIND) increase the opportunity for significant improvements in the diagnosis and treatment of TB and malaria. However further considerations for some of these products need to be addressed, such as the availability of point-of-care G6PD testing before they can be rolled out widely. The completion of the technical, regulatory and market access landscaping studies by IVCC also represents a foundational step in the roll out of new vector control tools in the region.
2. **COVID-19**: COVID-19 is impacting the activities of all PDPs, particularly in clinical trials. Three to nine-month delays of some activities are currently estimated. All PDPs have pivoted their activities to work that can be continued during the pandemic, conducted detailed risk assessments and are regularly updating funders on progress. PDPs currently estimate they can still complete all contractual activities by the end of the funding period. However, the final impact of COVID-19 on the work of PDPs is unknown.
3. **Progress against contractual activities**: The PDPs are generally tracking well against the contractual activities, given the mid-point in the funding cycle. FIND has delayed, deprioritised or cancelled some projects with adequate reasons provided. However as noted, the full impact of COVID-19 on product development activities is still unknown.
4. **Pipeline**: Over the funding period, there is evidence that the PDPs had a healthy distribution of products at different stages of the pipeline, with a significant number of products completing development since the launch of the PDPs: MMV 13, TBA 6, FIND 24 and IVCC 5 (2019).
5. **Access**: There was significant evidence of progress in the steps needed to ensure access to new products. For example, the PDPs reported a steady stream of products included in WHO guidance, obtaining regulatory approval and being distributed globally to LMICs. They also reported some activity in strengthening country capacity for product adoption.
6. **Gender equality & disability inclusion:** There was variable PDP reporting of activities to address gender equality. MMV was the most proactive in terms of initiatives, such as those for pregnant women and new-borns affected by malaria. All PDPs disaggregated their study data by gender and published studies on the gendered impacts of prevention, treatments and testing. IVCC is working with DFAT to strengthen their reporting. The PDPs did not report any specific activities to address disability inclusion.
7. **Efficiency and value for money:** The PDPs continue to demonstrate good value for money. The PDP model, pooling funds, working in partnerships, taking a portfolio approach represents an approach that can result in products being developed at a third or less of the cost of private sector development. The PDPs demonstrated large-scale health and economic impacts of their new products. MMV, TB Alliance and IVCC reported small variances between budgets and expenditure for 2018 and 2019, except for FIND which recorded bigger variances for both its overall and DFAT budgets in 2018.

8. **Review assessment of progress: This review's assessment of the progress of the PDPs funded by DFAT found that they are all making sufficient progress to constitute a full continuation of funding under the current funding agreements 2018-2023.**

PDP Partnerships and Collaborations in the Indo-Pacific

9. **Australian institutions:** The PDPs have many significant partnerships with Australian research institutes and universities. These are mutually beneficial, with the Australian partners providing technical know-how and networks while the PDPs can bring an output/impact-oriented focus.
10. **Links to other HSI investments:** There is a complex array of collaborations and communication between the PDPs and other HSI-funded investments in the Indo-Pacific. The RSP, Burnet and APLMA are each working with almost all the PDPs. This review found a need to continue to strengthen the communication and coordination around some of these connections.
11. **Strategic partners:** The Burnet Institute has an important strategic and operational relationship with each PDP and is also involved with several other HSI-funded programs. APLMA is also playing a key advocacy role in enabling access for some PDP products and is collaborating with MMV, IVCC and FIND.

DFAT's Support and Engagement

12. **CHS support:** CHS staff are playing a valued role in providing PDPs with programmatic updates, contextual knowledge and linking PDPs with other HSI-funded programs, Australian institutions and other actors. This has been particularly important given the PDPs' limited footprint in the region. CHS has also provided strategic input and leadership, such as through the PDPFG. The expertise, integrity and flexibility of CHS staff were integral to the value PDPs placed in their role. Ways in which DFAT could continue to strengthen this role were identified, particularly in facilitating linkages with the RSP, in health diplomacy working with APLMA (and VCAP) and in communicating with ASEAN.
13. **Regulatory strengthening:** The PDPs and several other interviewees identified regulatory strengthening as a key measure for improving access in the region and there have been examples of appropriate communication between the PDPs and RSP to date. MMV has had regular communication with TGA, FIND and TB Alliance will be seeking increased advice. Interviewees noted the need for increased communication on the RSP to broader stakeholders, an area that DFAT could support. There is potential for strengthening communication and coordination between actors interested in regulatory strengthening activities in the region including APLMA, Unitaid, BMGF, KOICA, GHIT and ASEAN. TGA has limited capacity to manage these demands and DFAT could play an increased role in this regard.

COVID-19 Response

14. **Role in COVID-19 response:** CEPI, FIND and MMV are playing key roles in the COVID-19 response. CEPI is the designated co-lead organisation for COVAX, the vaccines pillar of the ACT Accelerator. FIND is co-leading the ACT-Accelerator's diagnostics pillar with the Global Fund. The other PDPs have been supporting clinical trials, monitoring supply chains and taking steps to preserve gains made in TB and malaria and to continue diagnosis, treatment and prevention activities.
15. **Australian engagement and participation:** There is evidence of effective Australian engagement with CEPI via our representation on CEPI's Investors Council. In January 2020, CEPI allocated US$4.5million to the University of Queensland to advance development of the vaccine candidate, with preliminary results expected by the end of September 2020.

Reporting and monitoring, evaluation and learning

16. **PDP reporting:** There is considerable variation in PDPs' reporting of activities and results. The PDP Funder Report template goes some way in addressing this, but it is not completed consistently and to a high quality by all PDPs, who also produce their own annual reporting. The DFID reporting framework is completed by some PDPs and would be helpful as a supplement to reporting provided by PDPs to DFAT as it aligns with the PDP Fund MELF.
17. **Streamlining requirements:** The information provided to DFAT on progress of activities and financial expenditure and budgeting varies between the PDPs. There is scope to improve the consistency in the reporting requirements to DFAT, whilst not imposing any additional burden on the PDPs.

11. MANAGEMENT ACTIONS [EQ5]

11.1 CURRENT FUNDING PERIOD

The following management actions relate to DFAT (CHS) and the continuation of the PDP Fund during the current funding period from mid-2018 to mid-2023.

Priority of actions		Timeframe for response	
Critical		Short - within 6 months	S
Important		Medium - within 12 months	M
		Ongoing - for the duration of the funding phase	O

Management Actions	Priority & timeframe
1. **CHS to continue to fund the PDPs for the remainder of the current funding period at the same level.** Monitor the progress of contractual activities as a benchmark of progress, particularly for FIND, and the PDPs' overall financial reporting, while maintaining the flexibility required of core funding.	S
2. PDPs to continue to regularly **report** on the **impacts of COVID-19** on their work, as well as their contingency planning and risk mitigation measures. CHS to provide relevant support to maximise product development outcomes for the remainder of the funding period.	S
3. CHS to acknowledge that the PDPs are likely to experience considerable delays to some product development activities as a result of **COVID-19**, and if needed, make **provision for this in the final year of the funding cycle**, such as through no cost extensions.	O
4. CHS to work with PDPs and other partners to map **critical pathways** to support access for key products that have completed development or are nearing completion; with a focus on the Indo-Pacific. Identify the most appropriate actors to support at key points, including DFAT and its partners. Ensure that patient safety and country needs are prioritised, and the risks and benefits of product introduction are scrutinised.	S
5. CHS to continue to strengthen **linkages**, collaboration and coordination between **PDPs and other HSI-funded investments**. In particular, help to facilitate continued appropriate communication on regulatory strengthening activities between RSP, the PDPs and other stakeholders, and provide strategic health diplomacy on the same for APLMA initiatives.	M
6. CHS to continue to provide **strategic input into the CEPI Investors Council** and support **links** with **Australian institutions** with potential for involvement in the development of vaccines, therapeutics or diagnostics for **COVID-19.**	O

7. CHS to continue to provide **leadership** and **strategic input** and look for opportunities to strengthen key coordination mechanisms in product development and access, including through the **PDPFG.**	O
8. CHS to increase communication exchange and coordination on regulatory strengthening activities in support of the work of the **PDPs** and **RSP** with **Unitaid, BMGF, KOICA, GHIT and ASEAN.**	M
9. CHS to continue to find opportunities to broker **linkages** and support collaboration between PDPs and **Australian research institutions.**	O
10. PDPs to strengthen their ability to address **gender equality and disability inclusion** in their work, where relevant. CHS to link PDPs to relevant **advice** on the same.	M
11. PDPs to strengthen the **quality and consistency of their reporting** using the PDP Funder Template. CHS to encourage alignment of the pipeline phases for reporting using the table in Annex 7 and to explore integrating the DFID reporting framework or equivalent as a tool to clearly report on quantitative data required by donors.	M
12. CHS to **meet** with senior focal points at the **Burnet Institute on a periodic basis** to ensure coordination of the activities of PDPs, HSI-funded programs led by Burnet and other HSI investments. Continue to identify points of synergy and potential leverage between these programs together with Burnet.	S
13. CHS to maintain the **quality and integrity of DFAT's support** to the work of PDPs, related coordination mechanisms and the wider product development and access ecosystem by sustaining high levels of relevant expertise among the CHS staff and ensuring good systems for knowledge management and transition within CHS.	O

11.2 FUTURE CONSIDERATIONS

The following are considerations for any future phase of funding by DFAT in product development and access. It is noted that there is currently no Australian Government commitment beyond this phase of funding in mid-2023.

1. Consider restructuring future CHS funding to place **greater emphasis on end-to-end solutions which include demand-driven access activities.** This may be by requiring that PDP funding agreements include support for a greater proportion of access initiatives, funding new end-to-end initiatives which may include PDPs or funding activities that address specific access bottlenecks identified along critical product pathways. Ensure that a requirement of funding is that access initiatives are based upon country demand, capacity and need.
2. **Core funding** or equivalent **funding flexibility** should be maintained for future funding of product development.
3. Conduct an assessment of the progress and outcomes of **newer product development models** such as GHIT, the RIGHT Fund and MRI, lessons learnt from the ACT-Accelerator and review the operation of other Australian funding of product development research, such as grants made through the MRFF. Based upon the outcome of this assessment, consider whether and how Australia invests in product development going forward and whether it would be more effective to direct some of its funding towards newer models or approaches to product development.
4. Continue to fund **regulatory strengthening activities** in the Indo-Pacific, which has clear benefits in enabling product access and recognising the significant time that has been needed to establish TGA/RSP's role and relationships in the region during this phase of funding.
5. Ensure new **funding agreements** for HSI investments related to product development and/or access (including PDPs) include planning for, and evidence of, **regular and tangible collaborative activities** in order to increase coordination and efficiency of actors working in similar areas of product development and access. This should not be too prescriptive but would enable such activities to be acknowledged and funded.
6. Continue to support the identification of **pragmatic approaches for product access**, such as taking a critical pathways approach for the development and distribution of key products. Identify Australia's value add in supporting key points along these pathways alongside other actors, such as in the areas of regulatory strengthening, operational research and health diplomacy.
7. Develop a more **collaborative approach** to linking up and maximising the efficiency of all **DFAT's investments along the product development and access continuum,** managed by DFAT and other government departments**.** This may involve regular communication and sharing of information between all investments, and a combination of planned and opportunistic coordination of some related activities.
8. Continue contributing to the development of, and participation in, **formal governance and coordination structures for product development and access.** This could include participating in global and regional mechanisms to coordinate donor funding and progress product access and/or strategic input in the development or strengthening of new mechanisms, including those with potential to support global efforts in the Indo-Pacific such as Uniting Efforts. In parallel, ensure sufficient resourcing to enable experienced staff to continue to use **informal channels to support product development and access**. This includes drawing upon DFAT's networks, investments, experience and political leverage in the region to coordinate and link activities, provide regional insights and conduct health diplomacy.