Product Development and Access Partnerships – Questions and Answers
Updated: 22 March 2023

Information session and video recording

Questions	Answers
Will a recording of the information session be available?	**8 March 2023:** A video and transcript of the Product Development and Access Partnerships Information session held on 1 March 2023 is now available on our website. **See:** Product Development and Access Partnerships - Call for Proposals | indopacifichealthsecurity.dfat.gov.au

Technical and SmartyGrants related questions

Questions	Answers
The 'Download the preview form' function on the SmartyGrants site is not currently working and ends in an error message.	*UPDATED:* **21 March 2023.** The download preview form function is now working as expected.
SmartyGrants – as we do not have an ABN number, it seems we are not able to create an organization on the portal – is there a workaround that you can suggest? Error message on SmartyGrants: *Thanks for your email, currently only users within a registered organisation are able to share applications with other users within the same organisation. Only organisations with an ABN or NZBN are able to register as an organisation within SmartyFile.*	**21 March 2023:** SmartyFile is new function on SmartyGrants, it is an additional function available to organisations who have an ABN to simplify writing where they might have multiple staff working on a single submission. SmartyFile is a feature only available for organisations with an ABN. Importantly, an ABN is **not** a requirement for submitting a SmartyGrants application in this round. Further information is available on this here - https://applicanthelp.smartygrants.com.au/smartyfile/
Narrative description of the program logic: should we answer this question in the	**22 March 2023:** Sections 1a, 1b and 7b of the SmartyGrants form allow for applicants to provide

section: Demonstrate effectiveness, including providing detail on the following (350 words) **OR** is that a separate appendix? Or somewhere else?	information on elements of the proposal's objectives, intermediate outcomes and end of program outcomes, in relation to the program logic of the Partnerships for a Healthy Region initiative.
Same question about the narrative on our EML system/policy/principles. Should we answer this question in section 'demonstrate effectiveness (…)' or elsewhere?	**22 March 2023:** Please include your answer in the SmartyGrants form section 7b, and other sections as applicable.
Will a confirmation / acknowledgement of receipt be provided once we submit the proposal? If so, will it come in the shape of an email to the submitter, or just a pop-up message on SmartyGrants?	**22 March 2023**: Yes, SmartyGrants will display a message acknowledging you have submitted your application, and an email will also be sent with your submission number and a pdf version of your application to the email address you provided.

Submissions

Questions	Answers
Are eligible organizations able to submit more than one bid through Product Development and Access Partnerships?	**21 March 2023:** Yes, each application needs to meet the criteria as set out in the guidelines.
Does DFAT have any guidance regarding the process of organizations submitting more than one proposal? How might one application impact another's prospects?	**21 March 2023:** Each application will be evaluated and scored against the stated criteria in the guidelines.
Can eligible organizations submit a combined, single proposal with disparate components (inputs from country offices around the world)?	**21 March 2023:** Yes, as long as the application meets stated criteria in the guidelines.

PDP Organisation

Questions	Answers
What evidence is required to demonstrate that our organization is a PDP to be eligible for standalone funding? Could the PDP be an institution like a government university in a developing country? PDP definition per guidelines section 1.3: Is there any more information you can	**22 March 2023:** For the purpose of this calls for proposals, DFAT defines Product Development Partnerships as public-private partnerships that: • undertake research and development in relation to new vaccines, drugs, diagnostics or vector-control tools relevant for poverty-related diseases and disadvantaged populations in markets that are traditionally underserved by for-profit entities; • adopt a portfolio approach to product development, with clearly defined processes for anticipating and managing candidate attrition;

	blend the expertise and resources of a range of public and private partners, potentially including health and medical research organisations, industry, government agencies, civil society organisations and multilateral organisations; and
provide about a threshold of income or definition for "publicly funded", or can this be broadly interpreted?	• blend the expertise and resources of a range of public and private partners, potentially including health and medical research organisations, industry, government agencies, civil society organisations and multilateral organisations; and • have a track record of bringing products through the pipeline from discovery or early-stage trials to late-stage trials and market authorisation. Specifically, applicants need to be able to demonstrate they meet the eligibility criteria as set out in the guidelines. DFAT does not require organisations to have a specific level of public funding in order to be eligible.
Does the principal applicant have to be Australia-based?	**21 March 2023:** No.
How is 'partnership' defined in the question: 'Outline the objectives of the partnership?' - Is that the partnership between the PDP & DFAT? Is that the partnership as PDP (and thus presenting our organisation)?	**21 March 2023:** The partnership between the PDP and any other eligible organisations included in the application.
Eligibility Criteria: "The Applicant must provide proof of research and development activity". What would be acceptable proof?	**21 March 2023:** For example, publication of research attributable to organisation in the public domain.
Would a developing country institution require a partnership with responsibility to manage the funding?	**22 March 2023:** As stated in the guidelines, applicants must demonstrate effective governance and administrative structures including established and robust financial and human resource management systems and audit reporting.

Product and disease scope of Product Development and Access Partnerships Call

Questions	Answers
Could the scope include implementation, development of SOPs and utilisation guidelines?	**21 March 2023:** Only to the extent they are part of a wider portfolio submission that includes at least one of the key listed 'products' in the guidelines (section 3.2).
Is bio-marker discovery in scope? Is pre-feasibility work in scope?	**21 March 2023:** An application with only these products/projects included would not meet the criteria. They are in scope as long as they are part of a

	portfolio that meets the other criteria as set out in the guidelines, including *maturity and breadth of lead organisation's portfolio.*
Can we upload documents separately on the platform? As in – policies, strategies, complementary organisation? I can't find anywhere on the online platform where one can do that.	**21 March 2023:** DFAT requests that only information specifically requested via the SmartyGrants form is provided, allowing for fair and comparative evaluation of application.
Scope of portfolio: Does the requirement for a broad portfolio apply to the PDP organisation – which may have multiple products in Phase I or later for diseases that are outside the scope of the Call - or does it apply specifically to the activities within the Proposal itself? In other words, would DFAT consider a proposal that was based on one product drawn from the PDP's larger portfolio, as long as that single product was targeting a priority disease (or diseases) within the scope of the Call?

"Detail two or more candidate products in their portfolio which are in Phase One Trials or later": Do these products need to be for diseases in scope for the proposal (or would other diseases be possible, to show portfolio breadth and credibility)? | **21 March 2023:** The requirement for a broad portfolio applies to the PDP organisation.

In the case where the PDP targets multiple diseases, the proposal must include a portfolio of products where at least one disease targeted is within the disease scope of this call. Demonstration of candidate products at Phase One trial or later do not necessarily need to be in disease scope as outlined in guidelines. |
| STIs are within the scope of the PD and Access Call, while the Program Logic includes SRHR (EOPO3). Could a response to the PD and Access Call include activities directed to the treatment of maternal and neonatal sepsis, which are SRHR issues? | **21 March 2023:** For the Product Development and Access Partnerships Call diseases in scope are vector-borne diseases, sexually transmitted diseases, tuberculosis and neglected tropical diseases, as per the guidelines. Treatment of maternal and neonatal sepsis is not within scope for the Product Development and Access Partnerships Call. |
| Could the Product Development and Access Partnership utilize DFAT funds to incentivize generic manufacturers:
• To accelerate new product development and/or register new products in target countries?
• To enable global access pricing to ensure affordable pricing? | **21 March 2023:** DFAT would consider inclusion of that element in an application, as long as all other eligibility criteria is also met as set out in the guidelines. |
| Could products developed with co-funding and/or expiring funding be included in the proposal? | **21 March 2023:** Yes, as long as all other eligibility criteria are also met as set out in the guidelines. |

"Demonstrate relevant prior and ongoing research and development from the last five years" Can this be for diseases which are outside scope of the Asia Pacific region, but used to provide evidence of previous R&D?	**21 March 2023:** Yes.
Are the development and registration of quality control materials for Point of Care Testing (PoCT) for Infectious diseases within scope?	**22 March 2023:** Quality control materials fall outside the criteria for *Product scope* as set in the guidelines.
Could the scope include sustainable affordable in-country production of External Quality Assessment materials (bacterial and / or viral) used to monitor the testing capacity of laboratory sites in the developing country, allowing population access to quality diagnostic testing.	**22 March 2023:** External Quality Assessment materials fall outside the criteria for *Product scope* as set in the guidelines.
Are cryptosporidiosis and environmental enteric dysfunction considered in scope for this call?	**22 March 2023:** An application that includes cryptosporidiosis alongside other diseases that are on the stated disease list would be considered.
Are respiratory infections, including respiratory syncytial virus and pneumococcal infection also included in the products targeting infectious diseases of particular concern in this region?	**22 March 2023:** Applications must include products that target at least one disease as included in the stated list in Table 1 of the guidelines.

Would the following drug products fall under the definition of New Products:
     1.   Generic formulations of drug products which are not currently available in target countries?
     2.   Fixed dose combination of drug products which are not currently in target countries?
	22 March 2023: DFAT is seeking proposals from applicants with demonstrated relevant prior and ongoing research and development of **new products, new formulations (e.g., paediatric) or new indications**, in addition to all other eligibility criteria as set out in the guidelines.

Could the Product Development and Access Partnership utilize DFAT funds to procure newly developed and globally registered products: 1. To conduct implementation research studies in target countries? 2. To catalyze product uptake in target countries? 3. For product donations for programmatic use in target countries where regulatory approval mechanisms do not exist?	**22 March 2023:** DFAT would consider inclusion of these elements as part of a broader application that met the stated criteria. These elements alone would not meet eligibility criteria for this Call.

Are both R&D and Access elements are in scope? Should we focus on late R&D (not necessarily excluding basic science e.g., biomarkers development, but focusing on the latter stages instead) and early access (e.g. pilot studies, feasibility studies, would be in scope) rather than late access (e.g. work on regulatory, market shaping would not be 'excluded', but not an aspect we should focus on too much)? Are these assumptions correct?	**22 March 2023:** Both R&D and access elements are in scope. DFAT would consider applications that span the breadth of activity from discovery to market authorisation and market shaping, and requests applicants take into account the evaluation criteria as listed in 'Table 2: PDAP Evaluation Criteria' and relative weightings.
Would deployment of an appropriate digital adherence technology for TB treatment be in scope for this grant?	**22 March 2023:** DFAT would consider inclusion of these elements as part of a broader application that met the stated criteria. This element alone would not meet eligibility criteria for this Call.
Would a proposal focused on the development of a pipeline of drug products, at various stages, that address HIV prevention in women (alone and/or in combination with prevention of other STIs) be responsive to the call for proposals?	**22 March 2023:** Yes.
Would a proposal focused on the development of a pipeline of drug products focusing on HIV (or other STI) prevention alone and/or in combination with a contraceptive be responsive to the call for proposals?	**22 March 2023:** Contraceptive products are not included in this Call.
Can one application from an institution for the Product development and Access partners contain more than one product e.g., STI product and a NTD product; or should the same institution submit a separate application for each product.	**22 March 2023:** DFAT will consider applications with multiple products targeting different diseases.

Trial Sites

Questions	Answers
Would DFAT support activities outside the region, such as a clinical trial in Africa that was part of a multi-site trial that included at least two sites in the Indo-Pacific, if the clinical data would support an access strategy in the Indo-Pacific?	**21 March 2023:** Yes.

Geographic scope of Product Development and Access Partnerships Call

Questions	Answers
The stated target region is Pacific and South-East Asia region. Are you referring here to WHO definition of region e.g., SEARO (South-East Asia and WPRO (Western Pacific)	**21 March 2023:** Countries in scope are: Pacific: Kiribati, Federated States of Micronesia, Fiji, Nauru, Niue, Palau, Papua New Guinea, Republic of Marshall Islands, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu Southeast Asia: Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Thailand, Timor-Leste, Vietnam.
It is clear that the selected project needs to benefit the Asia Pacific Region partners. Does all the funded work need to be executed in the Asia Pacific region or can part of the work include other LMIC regions in the world, if Asia-Pacific region is also an end beneficiary?	**21 March 2023:** Part of the work can include other LMIC regions, if the Asia-Pacific region is also an end beneficiary. Not all the funded work needs to be executed in the Southeast Asia and/or Pacific regions.
Regarding the criteria on *track record in the Asia-Pacific region*, does that need to be demonstrated with product in development, or can be demonstrated with additional studies and projects that support current product in development?	**21 March 2023:** DFAT is looking for applicants to demonstrate their prior activity in the Southeast Asia and/or the Pacific regions to illustrate their understanding of regional context relative to product development and access needs.
Is there a geographic restriction on where the funds can be spent? Or could funding support activities elsewhere (e.g., Brazil, Africa, Geneva, etc.) if funding is for work on diseases which will be of regional relevance? Stated otherwise: how much of the funds need to be directly spent in the region?	**21 March 2023:** Part of the work can include other regions, if the Asia-Pacific region is also an end beneficiary. Not all the funded work needs to be executed in the Southeast Asia and/or Pacific regions. There is no specific requirement to spend a certain amount in the region.

Outcomes of Product Development and Access Partnerships Call

Questions	Answers
You have listed a number of intermediate objective (section 2.2 from application guideline) and of end objectives (section 2.3 from application guideline) that need to be achieved. I would like to ask if all the objectives need to be achieved during the project; or if only one listed intermediate	**21 March 2023:** Proposals should include the intermediate outcomes (section 2.2 of guidelines) and end of program outcomes (section 2.3 of guidelines) that the applicant plans to achieve within the time and scope of their proposal. DFAT will require successful applicants to share a MEL framework during the inception period.

Questions	Answers
objective and one listed end objective, need to be achieved?	

Referees and Organisational Certificate

Questions	Answers
Referee information per application form: Could you please describe "what constitutes a business association with the organisation"? Would it be permissible to have referees in the following situations? • The referee is a leader in an organisation from which our organisation has in-licenced an asset in our portfolio? • The referee is a leader in an organisation from which our organisation has previously received a substantial investment / funding?	**21 March 2023:** Yes. Yes.
Most accompanying documents to the RfP contain a checklist. Are these checklists only meant to guide our thinking, or are we expected to tick the boxes, sign and submit these checklists as appendices on SmartyGrants?	**22 March 2023:** Please complete the forms, sign and submit them on SmartyGrants as part of your application.

Indirect rate, budget and personnel

Questions	Answers
What is DFAT's maximum allowable indirect costs rate?	**22 March 2023:** DFAT will limit indirect costs (ie. Overheads/Administrative Support Costs) for Product Development and Access Partnerships to a maximum of 15% of direct costs; and for Projects and Strategic Partnerships to a maximum of 10% of direct costs.
On key personnel: May a consultant to the lead organization (rather than a staff member thereof) be listed?	**22 March 2023:** Yes.
Please provide definitions for the columns in the budget template and SmartyGrants in relation to applicant contributions and partner contributions?	**22 March 2023:** **In the <u>SmartyGrants form:</u>** In SmartyGrants, we request details of *funding from other sources* in two locations. Under the heading:

	Funding from other sources *Include details of future funding for PDP (lead organisation) by donor and financial year (FY2022-23 to FY2026-27) in AUD',* please include <u>all other donor funding for the PDP</u> (not just this proposal). Under the heading: ***Budget*** *Other sources funding,* please include <u>other donor funding for this proposal.</u> This should align with amounts provided in Column F of the budget template (see below). In addition, under the heading: **Budget** *Organisation contribution* refers to the sum of *Applicant contribution* (Column D) and, if applicable, *Counterpart/partner contribution* (Column E) in the Budget template. **In the <u>budget template:</u>** Column D: Applicant contribution relates to monetary contributions towards this proposal from the applicant. Column E: Counterpart/partner contribution relates to monetary contributions from consortium members for this proposal, if relevant. Column F: Other partner contribution relates to nominate monetary contributions from other donors for this proposal.
Do we need to include in-kind contributions in the budget template and in SmartyGrants or only monetary contributions?	**22 March 2023:** DFAT only requires inclusion of monetary contributions, not in-kind contributions.
"Please share details of future funding for PDP by donor and financial year" Should this describe total funding for the PDP, or just co-funding for the activities as proposed within the scope of the proposal (as a sub-set of total)?	**22 March 2023:** Total funding for the PDP
The current Product Development and Access Partnerships program is a five-year program. May we confirm that is correct? May we also confirm that successful grants are expected to commence (around) 1 July 2023? And the concluding end date?	**22 March 2023:** We request applicants provide budget for a five-year program period. Exact details of timing and tranche payments will be determined during contract negotiations.

You ask for budget by Australian fiscal year. The first of these, 2022-23, is nearly finished. How should we account for this? What should we consider as the start date of the desired funding?	
Budget template guidance notes for applicants: "Detailed budgets will be determined during the collaborative design process following partner selection." AND "During agreement negotiations an expanded budget and expenditure template will be made available for partners, that will further outline expectations on expenditure reporting." Are these the same process?	**22 March 2023:** Yes, these steps will occur together following partner selection.
Expenditure reporting sections- specifically column I, and columns N, O, P and R. Can you confirm that those should be left blank?	**22 March 2023:** Yes.
In relation to column H on "Proportion of DFAT Funds in Total Financing (%)". Are there any upper or lower limits here?	**22 March 2023:** No.
Is an investigator eligible to be a co-investigator on a Product Development and Access Partnership proposal, if they are leading a Regional Health Partnership Proposal and co-CI on another Regional Health Partnership Proposal? Are there any limits on this?	**22 March 2023:** DFAT would consider this on a case-by-case basis. Noting that the Principal Investigator must be able to commit to any and all successful proposals.