

**Selected Health R&D Demonstration Projects:
Indicators for Measuring Success**

Analysis by the Secretariat

March 2015

SECTION 1: Process Indicators Approved by Decision WHA67(15)

PROJECT: The Leishmaniasis Global R&D & Access Initiative - Drugs for Neglected Diseases initiative
OVERALL SCORE (out of 14): 12

Part 1 – Project Plan (maximum 8 points)

	Area	Yes	No	Partial	SCORE	Comment/Details
1	Project Plan					
1.1	Major milestones identified	Yes			1	Clear milestones provided in the project plan (2015-2019) under each specified objective and activity.
1.2	Activities identified in a chronological order	Yes			1	The project has 4 objectives, each with specific activities outlined. The 4 objectives are chronologically staggered over the years of implementation of the project.
1.3	Organizations/institutions responsible for each activity identified, with clear roles for each of them	Yes			1	Implementing partners for each objective and activity have clearly been defined.
1.4	Coordination mechanisms and governance in place	Yes			1	DNDi seeks to exploit its extensive experience as a PDP in this field to coordinate and manage a variety of efforts on increasing R&D and access to medicines for leishmaniasis.
1.5	Agreed timelines for completion of each activity	Yes			1	The activities under each of the four objectives have clear timelines staggered chronologically across 2015-2019.
1.6	Deliverables/outputs identified for each activity	Yes			1	Clear deliverables / outputs identified for each activity

1.7	Cost of each activity identified	Yes			1	Cost of each activity under the four objectives is clearly identified
1.7	Number of implementing partners	More than 5			1	
TOTAL (out of 8)					8	

Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for number of implementing partners:

- 0-1 partner(s) = 0
- 2-5 partners = 0.5
- More than 5 partners = 1

Part 2 – Financing (maximum 6 points)

	Area	Y e s	N o	Pa rti al	SCORE	Comment/details
2	Financing					
2.1	Overall budget defined	Ye s			1	32,000,000 EUR (of which 9,187,500 EUR is secured and a further 6,100,000 EUR is pledged). Note: Below calculations will take into account both secured and pledged amounts.
2.2	% Funds pledged for first year of the project	72.80%			1	First year budget: 7,950,000 EUR, of which 5,787,500 EUR is covered through secured or pledged funds.
2.3	% Funds pledged for second and third years of the project	35.53%			1	Total second and third year budget: 19,950,000 EUR, of which 7,087,500 EUR is covered through secured or pledged funds.
3	Engagement of donors					

3.1	Number of funders	More than 3	1	Current funders include The Bill and Melinda Gates Foundation, Medecins Sans Frontieres, DFID (UK), Ministry of Health, France and the French Development Agency, GHIT and Wellcome Trust. Discussions with a variety of other potential donors are underway.
TOTAL (out of 6)			4	

Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for funds pledged for the first year of activities:

- Funds pledged corresponding to 0-50% of first year budget = 0
- Funds pledged corresponding to 50%-75% of first year budget = 1
- Funds pledged corresponding to more than 75% of first year budget = 2

Scoring for funds pledged for second and third years of activities:

- Funds pledged corresponding to 0-30% of 2nd and 3rd year budget = 0
- Funds pledged corresponding to 30%-60% of 2nd and 3rd year budget = 1
- Funds pledged corresponding to more than 60% of 2nd and 3rd year budget = 2

Scoring for number of funders:

- 0-1 funder(s) = 0
- 2 to 3 funders = 0.5
- More than 3 funders = 1

PROJECT: Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty - Medicines for Malaria Venture

OVERALL SCORE (out of 14): 9

Part 1 – Project Plan (maximum 8 points)

	Area	Yes	No	Partial	SCORE	Comment/Details
1	Project plan					
1.1	Major milestones identified	Yes			1	Clear milestones have been identified along the chronological timeframe of each activity.
1.2	Activities identified in a chronological order	Yes			1	The two broad project activities are exploiting the pathogen box and capacity building, each of which has several sub-activities defined. Activities and sub-activities clearly identified by first year, second year and years three to five.
	Coordination mechanisms and governance in place	Yes			1	The project will be overseen by MMV scientific leaders and will be evaluated through contributions from MMV's expert scientific advisory committee (ESAC).
1.4	Agreed timelines for completion of each activity	Yes			1	Clear timelines exist for the completion of the sub-activities under the two main project activities.
1.5	Deliverables/outputs identified for each activity	Yes			1	Clear expected deliverables/outputs have been identified for each activity.
1.6	Cost of each activity identified	Yes			1	Cost of each activity has clearly been identified in total and by year.

1.7	Number of implementing partners	More than 5	1	MMV will be leveraging its extensive network of partners for every aspect of the project - pharmaceutical companies, government agencies, other PDPs and academic and research institutions, among others.
TOTAL (out of 8)			8	

Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for number of implementing partners:

- 0-1 partner(s) = 0
- 2-5 partners = 0.5
- More than 5 partners = 1

Part 2: Financing

	Area	Y e s	N o	Pa rti al	SCORE	Comment/details
2	Financing					
2.1	Overall budget defined	Ye s			1	The total budget for the project is USD 11,500,000. Note: Below calculations will take into account both secured and pledged amounts.
2.2	% Funds pledged for first year of the project				1	First year budget: USD 1,360,000
2.3	% Funds pledged for second and third years of the project		0.00%		0	Second and third year budget: USD 4,920,000
3	Engagement of donors					
3.1	Number of funders		0		1	This project is based on “The Pathogen Box”, which is funded by a grant from The Bill and Melinda Gates Foundation.

TOTAL (out of 6)	3
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Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for funds pledged for the first year of activities:

- Funds pledged corresponding to 0-50% of first year budget = 0
- Funds pledged corresponding to 50%-75% of first year budget = 1
- Funds pledged corresponding to more than 75% of first year budget = 2

Scoring for funds pledged for second and third years of activities:

- Funds pledged corresponding to 0-30% of 2nd and 3rd year budget = 0
- Funds pledged corresponding to 30%-60% of 2nd and 3rd year budget = 1
- Funds pledged corresponding to more than 60% of 2nd and 3rd year budget = 2

Scoring for number of funders:

- 0-1 funder(s) = 0
- 2 to 3 funders = 0.5
- More than 3 funders = 1

PROJECT: Development of Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases – African Network for Drugs and Diagnostics Innovation

OVERALL SCORE (out of 14): 9

Part 1. Project Plan (maximum 8 points)

	Area	Yes	No	Partial	SCORE	Comment/Details
1	Project plan					
1.1	Major milestones identified	Yes			1	Clear milestones have been identified for the timeline of the project (2014-2019).
1.2	Activities identified in a chronological order	Yes			1	Activities identified clearly in chronological order, with room remaining for flexibility and adjustments based on outcomes.
1.3	Organizations/institutions responsible for each activity identified, with clear roles for each of them	Yes			1	The roles played by ANDI, ANDI Centres of Excellence as well as China NDI and other partners have been clearly identified in relation to each activity, with additional room available to bring in more partners.
1.4	Coordination mechanisms and governance in place	Yes			1	Project coordination and management will leverage the experience and networks of ANDI and China NDI.
1.5	Agreed timelines for completion of each activity	Yes			1	Clear timelines established for completion of each project activity over the lifetime of the project (2014-2019).
1.6	Deliverables/outputs identified for each activity	Yes			1	Clear expected deliverables/outputs have been identified for each activity.

1.7	Cost of each activity identified	Yes			1	Cost of each activity clearly identified
1.8	Number of implementing partners	More than 5			1	Implementing partners include five ANDI centres of excellence, 4 Chinese research institutions associated with China NDI plus other partners such as EASE-Medtrend.
TOTAL (out of 8)					8	

Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for number of implementing partners:

- 1 partner = 0
- 2 to 5 partners = 0.5
- More than 5 partners = 1

Part 2. Financing(maximum 6 points)

	Area	Y e s	N o	Pa rti al	SCORE	Comment/details
2	Financing					
2.1	Overall budget defined	Ye s			1	The overall budget for 2014-2019 is USD 19 million.
2.2	% Funds pledged for first year of the project				1	First year budget (including pre-implementation activities): USD 9,000,000. ANDI and China NDI have spent approximately USD 250,000 secured with USD 50,000 pledged for biomarker discovery in the first year by China NDI.
2.3	% Funds pledged for second and third years of the project	0.00%			0	0

3	Engagement of donors			
3.1	Number of funders	0	1	ANDI and China NDI have self-funded and pledged some funds for the early stages of pre-implementation and implementation of the project.
TOTAL (out of 6)			3	

Scoring for Yes, No, Partial response questions:

- Yes = 1
- No = 0
- Partial = 0.5

Scoring for funds pledged for the first year of activities:

- Funds pledged corresponding to 0-50% of first year budget = 0
- Funds pledged corresponding to 50%-75% of first year budget = 1
- Funds pledged corresponding to more than 75% of first year budget = 2

Scoring for funds pledged for second and third years of activities:

- Funds pledged corresponding to 0-30% of 2nd and 3rd year budget = 0
- Funds pledged corresponding to 30%-60% of 2nd and 3rd year budget = 1
- Funds pledged corresponding to more than 60% of 2nd and 3rd year budget = 2

Scoring for number of funders:

- 0-1 funder(s) = 0
- 2 to 3 funders = 0.5
- More than 3 funders = 1

SECTION 2: Analysis of the Extent of Innovative Components, as requested by Decision WHA67(15)

Proposed Innovation Indicators

The following evaluation framework is based upon the assessment framework used to evaluate the innovative aspects of the demonstration projects at the final stage of the selection, which was in turn based on the six questions clarifying innovative aspects of proposals that were approved by Member States at the Global Technical Consultative Meeting on 05 December 2013. It is also informed by the specific request by Member States for “the addition of an analysis of the extent of innovative components being implemented by the projects, including financing, the use of open access models, multisectoral research platforms, and delinkage, among other criteria” found in WHA67(15). Strong emphasis is placed throughout the assessment framework on the involvement of developing and endemic countries.

The scoring associated with this assessment framework is a quantification of the analysis carried out by the former Chair and Vice-Chair of CEWG on 10 March 2014. That assessment used the following criteria:

- GREEN: Will demonstrate a CEWG recommendation
- YELLOW: Weakly demonstrates a CEWG recommendation
- RED: Will not demonstrate a CEWG recommendation

The current framework assigns the following numerical grades to those categories based on that assessment as follows:

- 2: Will demonstrate a CEWG recommendation
- 1: Weakly demonstrates a CEWG recommendation
- 0: Will not demonstrate a CEWG recommendation

Score	INNOVATION INDICATORS	
	INNOVATIVE COMPONENTS	DESCRIPTION OF CRITERIA
	Delinkage	The project clearly delinks the cost of research from the price of the product.

	Open knowledge approaches		The project makes available for others to access and use research data and results.
	Licensing for access		The project uses licensing terms that ensure access and affordability.
	Financing		The project uses pooled funds, milestone prizes, and other innovative financing mechanisms (e.g. taxes, etc) or sources of funds (e.g. from developing countries, endemic countries or the emerging economies)
	Coordination	Multi-sectoral/ disciplinary research platforms and/or partners	The project links data and information coming from multiple sources and/or engages with a diversified array of partners, particularly in developing and endemic countries
		Cross-regional	The project involves institutions coming from multiple countries and regions.
	Capacity building and technology transfer		The project builds capacity in developing and endemic countries. The project uses transfer of technologies as a means to decrease capacity in developing and endemic countries.

Assessment of Selected Demonstration Projects

	The Leishmaniasis Global R&D & Access Initiative Drugs for Neglected Diseases initiative (DNDi) <i>(Combining the selected leishmaniasis projects from DNDi and USFDA)</i>	
Score	INNOVATIVE COMPONENTS	ANALYSIS
2	Delinkage	The project is partly open source, utilising the public domain. The project also utilises DNDi's IP policy, adopted in 2004 which focuses on ensuring drugs are affordable and accessible. Licensing terms will ensure the final product is to be available at manufacturing cost with minimal margin in all endemic countries regardless of income

		level.
2	Open knowledge approaches	The project incorporates several open knowledge approaches, including a Drug Accelerator Consortium in collaboration and a Data Sharing Platform in coordination with WWARN to identify determinants of treatment efficacy and effectiveness. The Drug Accelerator Consortium is set to be launched towards the end of 2014 / beginning of 2015. It will pool resources, compounds, and expertise across companies, expediting identification and selection of candidates for promising new chemical entities from lead optimisation to pre-clinical research. The Accelerator would reduce costs and time of the discovery phase of R&D while adhering to DNDi licensing policies. Outcomes are to be published into the public domain to catalyse further research. The Data Sharing Platform will create an open clinical and biological database of anonymised patient data for research to resolve scientific questions emanating from single studies.
2	Licensing for access	DNDi has established licensing terms with pharmaceutical partners, with an emphasis on royalty-free, non-exclusive, sub-licensable licenses, worldwide research and manufacturing rights, and ensuring the final product is available at manufacturing cost with minimal margin in all endemic countries regardless of income level.
2	Financing	The project, currently leveraging existing grant resources from The Bill and Melinda Gates Foundation, MSF and DFID, is committed to pooled funding and innovative financing. The study commissioned

			by DNDi on the concept of an international pilot pooled fund and presented at the 07 May 2014 stakeholder meeting is available online. In addition to being involved in the pooled funding for selected demonstration projects, other pooled funds have been approached for partnerships, such as Innovative Medicines Initiative (IMI), EDCTP, and the Global Health Initiative Technology Fund (GHIT), as well as non-traditional donors and emerging economies. The project also utilises milestone and end prizes.
2	Coordination	Multi-sectoral/disciplinary research platforms and/or partners	The projects partners with the LEAP clinical platform in Africa, EDCTP, IMI, CSIR and OSDD, in addition to DNDi's pharmaceutical and academic partners. Emphasis is strongly placed throughout on innovative alliances with pharmaceutical and biotechnology companies and academia. The project leverages DNDi's extensive network of public and private partners.
		Cross-regional	The project is based on an optimisation and co-ordination of already existing initiatives all around the world. As a successful PDP, DNDi has experience with engagement of actors from all over the globe, particularly in endemic countries; pharmaceutical and biotechnology companies; NGOs; PDPs; and governments) by leveraging assets, capacities, and expertise.

2	Capacity building and technology transfer	The project emphasises capacity building via prizes, including a qPCR diagnosis Prize that has a capacity building pre-requisite. Coordinated activities with endemic countries will enhance clinical trial capacity in Asia, Africa and Latin America through project platforms and other research networks. The project involves technology transfer components such as training courses and set-up of colony and infectivity experiments. The project also seeks to contribute to improving clinical trial capacities in these regions.
TOTAL SCORE (out of 12): 12		

Score	Exploiting the Pathogen Box: Medicines for Malaria Venture (MMV)	
	INNOVATIVE COMPONENTS	ANALYSIS
2	Delinkage	The project is focused on pre-competitive research with deliverables being early series (i.e.. a robust Hit-to-Lead series). However, the proposal follows a fully open source and open knowledge innovation approach and leverages MMV's expertise as a PDP to link to next-step mechanisms in the R&D process that fulfill the criteria of delinkage, including pricing constraints in late stage contracts and emphasis on access and affordability.
2	Open knowledge approaches	The project is envisioned as an open source global collaboration, with MMV acting as the central hub of a network of scientists across many different neglected disease areas. The aim is to exploit publicly disclosed hits from the "Open Source Pathogen Box" and make sure key data is publicly available as early as possible. The project emphasises open innovation as a way to build knowledge and experience as well as stimulating interest in the

			research for neglected diseases and leverages MMV's existing open source partners and processes.
2	Licensing for access		This project utilises the public domain and links the results to well-established PDP frameworks for licensing to ensure access and affordability. The Pathogen Box "would be provided on request, free of charge, and not subject to license, and in return, Pathogen Box users are asked to guarantee that the resulting data be published and placed in the public domain within two years of its generation. MMV will not seek upfront rights in the output of research - or any resulting products - conducted by Pathogen Box users." It is further proposed that "the standard MMV or DNDi contract structures would be in place for the investment in the lead optimization and clinical development which would ensure that subsequent financial commitments are linked to ensuring the maximum access to any final medicine." ¹
1	Financing		Although primarily based in traditional grant-based financing, the project seeks to act as a catalyst accelerating the drug discovery process leading to potential breakthroughs across a broad catalogue of neglected diseases, reduce early stage financial risks and avoid duplication of efforts thereby leading to sustainability of the model. MMV is also committed to the concept of pooled funding for the selected demonstration projects and has added "Endemic Country Challenge Grants" as a capacity building activity to the proposal.
2	Coordination	Multi-sectoral/disciplinary research platforms and/or partners	The Selection Committee for the Pathogen Box will be comprised of senior scientists and thought leaders from the global neglected diseases

¹ Answers to Additional Questions on Innovation (Question 3), available online at: http://www.who.int/phi/implementation/MMV_documents.pdf

			community, along with representatives from PDPs, industry, academia, and funding agencies. The project leverages MMV’s network of partners and avoids potential duplication of work.
		Cross-regional	MMV will continue to work with its network of partners all across the globe, including India, Africa and South America. The pathogen is freely available to researchers in institutions around the globe.
2	Capacity building and technology transfer		After discussions at the stakeholder meetings, capacity building became one of the main objectives of the project proposal. This will be done through endemic country challenge grants. As stated previously, the Pathogen Box will be freely available to all interested researchers and MMV will leverage its partnerships in LMICs to ensure capacity building occurs.
TOTAL SCORE (out of 12): 11			

	Development of Easy-to-Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases African Network for Drugs and Diagnostics Innovation (ANDI), Chinese Network for Drugs and Diagnostics Innovation (China NDI)	
SCORE	INNOVATIVE COMPONENTS	ANALYSIS
1	Delinkage	The primary focus of the project is pre competitive research, with the starting point being publicly available and financed genome sequences. It leverages public sector funding, open knowledge / open source approaches and no royalties will be applied to public sector licenses. Recovery of costs is not the objective of the proponents.
2	Open knowledge approaches	The starting point for the project is publicly available and financed genome sequences and the project utilises an open platform for sharing R&D results and involving new collaborators. The main focus of the project is an open knowledge approach to South-South

			collaboration between ANDI and China NDI and associated partners.
2	Licensing for access		All background IP developed to date will be publicly documented along with any new program IP. This will be made freely available to all partners for the purposes of R&D, manufacture and access. Licensing agreements will be focused on ensuring public access to research results, unhindered manufacture and access to affordable final products.
2	Financing		The project combines voluntary pooled financing by government and other donors in the short term and government-approved taxes on specific products/services in the medium-term. These leveraged funds would be used to support R&D grants, innovation award schemes as well as loans or social venture initiatives or prizes to address unique R&D/manufacture and access issues. The project also leverages funding from partner organizations.
2	Coordination	Multi-sectoral/disciplinary research platforms and/or partners	The starting point for the project is leveraging the platforms, expertise and technology available to China NDI and associated partners as well as the expertise of ANDI and associated centres of excellence.
		Cross-regional	The project is a South-South collaboration between established African and Asian networks, partners and institutions.
2	Capacity building and technology transfer		This is a project led by an African institution leveraging developing and endemic country resources and expertise, and it inherently involves capacity building. It also involves active engagement with LMIC manufacturers and technology transfer (leveraging China NDI's databases and technology to develop similar infrastructure, databases and networks in Africa) between China NDI and ANDI and partner institutions. The focus of the

		<p>project – development of diagnostics and incorporation into modern devices i.e. remote/mobile control system with data transfer capabilities to enable easy and real time access to information and test results could also serve to strengthen the development of associated health systems in Africa and potentially beyond.</p>
TOTAL SCORE (out of 12): 11		