

KEY:
Green = Will demonstrate a CEWG recommendation
Yellow = Weakly demonstrates a CEWG recommendation
Red = Will not demonstrate a CEWG recommendation

SELECTED DEMONSTRATION PROJECTS: EXAMINATION OF INNOVATIVE ASPECTS - ORIGINAL RESULTS

10 March 2014

Project	Delinkage	Open knowledge innovation	Licensing for access	Financing mechanisms	Coordination mechanisms	Capacity-building
The Visceral Leishmaniasis (VL) Global R&D & Access Initiative Drugs for Neglected Diseases initiative (DNDi) Submitted via AFRO and EMRO	Partly open source / utilizes public domain. Final product to be available at manufacturing cost with minimal margin.	Open source collaborative platform for data sharing.	Non-exclusive / equitable licensing; IP policy focused on stringent affordability and access requirements.	Uses innovative incentive mechanisms, including milestone prizes. Leverages different funding mechanisms in a collaborative manner. Seeks funding from developing countries.	Engages new and existing partners in both delivery and funding, including endemic countries. Open knowledge and sharing platform.	Utilizes mechanisms focusing on both technology transfer and capacity building in affected countries, including the potential to improve clinical trial capacity.
<i>(now combined with)</i> Development of Class D CpG ODN (D35) as an Adjunct to Chemotherapy for cutaneous leishmaniasis and Post Kala-Azar Dermal Leishmaniasis (PKDL) United States Food and Drug Administration (US FDA), et al. Submitted via AMRO	Clear on delinkage: No royalties to be applied to public sector institutions or institutions using public sector funds; will not attempt to recover R&D cost.	Results will be open and transferrable; Seeks to utilize broad consortium under umbrella of WHO. In general IP protected and not open knowledge, but open collaborative approach.	Equitable and humanitarian licensing approach.	Traditional grant-based funding. Focus on leveraging of funds from new actors and key States and institutions through collaboration with WHO.	WHO-based consortium including endemic countries and other key Member States and actors in the fields of CL and PKDL.	Manufacturing platform easily transferrable; expects to choose manufacturing sites in endemic countries and engage actively with LMIC manufacturers.
Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty Medicines for Malaria Venture (MMV) Submitted via EURO	Focused on pre-competitive research and is not linked directly to providing new products. However, the proposal follows a fully open source and open knowledge innovation approach and links to next-step mechanisms in the R&D process that	Open source approach to collaboration and knowledge sharing.	Utilizes public domain.	Traditional grant-based funding – although attempt will be made to try to spread out financing needs between the partners involved.	Use of selection committee to select and prioritize profile of the pathogen box, thus involving and linking multiple stakeholders and avoiding duplication of work.	Universally available to any interested researcher. Partners in LMICs in South America, Africa and Asia.

Project	Delinkage	Open knowledge innovation	Licensing for access	Financing mechanisms	Coordination mechanisms	Capacity-building
	fulfill these criteria.					
Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases African Network for Drugs and Diagnostics Innovation (ANDI), et al. Submitted via AFRO	Mostly pre-competitive research. However, also states that public financing will ensure delinkage without providing specific information or evidence on how this will be achieved.	Open platform for sharing R&D results and involving new collaborators.	Licensing agreements ensuring public access to data, manufacture and unhindered access to final product to secure affordable products.	Interlinked financing mechanism. Provides details on voluntary pooled financing by governments and potentially private entities through donations and taxes and potentially used to fund grants and prizes.	Use of ANDI network; positive method to test ANDI as a coordination mechanism. The potential for partnerships is very high.	Project based in Africa led by African actors. Will engage with LMIC partners.

REVISED DEMONSTRATION PROJECT PROPOSALS: EXAMINATION OF INNOVATIVE ASPECTS - RESULTS
07 November 2014

Multiplexed Point-of-Care test for acute febrile illness Translational Health Science and Technology Institute (THSTI), India, et al. Submitted via SEARO	States that public funding will ensure delinkage and clearly outlines the factors which will contribute to ensuring delinkage.	Uses PDP model. Knowledge sharing and use of IP pooling within the consortium but no wider access (details on extent of data sharing with external actors unclear)	Non-exclusive equitable licensing for final products. Licensing terms will stipulate commitment to making the final product(s) available at minimal margins. If manufacturer does not comply with quality, affordability and access aspects of the agreement, the license may be revoked.	Intends to create a pooled fund via WHO to pool government donations. Seeks funding from developing countries and to engage non-traditional donors.	Clear network of partners and coordination plan laid out. Brings together LMIC governments, manufacturers, academia and other partners. Represents North-South as well as South-South collaboration.	Very clear with respect to building capacity in developing countries Will engage LMIC manufacturers and engagement with LMIC countries creates potential for co-development and transfer of technology to firms or institutions in less developed countries.
Demonstration of the potential of a single dose malaria cure of artemether-lumefantrine through reformulation in a nano-based drug delivery system Council for Industrial and Scientific Research, South Africa, et al. Submitted via AFRO	States that public funding will ensure delinkage. However, there is a lack of specific information and evidence on how this will be achieved.	Some evidence of an open knowledge approach between partner organizations, but not with external actors.	Non-exclusive licensing and IP to be held by public sector. No details on additional policies and how low-end price will be specifically secured. South African IP law allowing the State royalty-free licensing is mentioned, but this is a prerogative of the state, not a policy of the proponents and is not universal.	Although this is a classic consortium proposal which relies upon grants from existing funders, it seeks to engage BRICS as potential donors as well as, potentially, pooled funding.	Clearly outlines a coordination mechanism between various African governments and institutions as well as with industry.	Inherently includes capacity building due to geographical area and institutions involved.

<p>Development of a Vaccine Against Schistosomiasis based on the recombinant Sm14 a member of the fatty Acid Binding Protein: Controlling transmission of a disease of poverty¹</p> <p>Oswaldo Cruz Foundation (Fiocruz), Brazil, et al.</p> <p>Submitted via AMRO</p>	<p>States that the public financing will ensure delinkage together with the low cost of development to date, clear institutional policies committed to access and affordability and maintaining low cost of development in scaling up, as well as use of non-proprietary components and offset costs from veterinary use.</p>	<p>Project has consistently and deliberately used open knowledge innovation and approaches in pre-competitive phases and is transitioning to a patent-protected format due to potentially lucrative livestock market, though this is combined with equitable licensing requirements for human use.</p>	<p>Licensing terms with the manufacturer stipulate bulk supply in endemic countries at cost-plus prices, part of the institution's "equitable licensing orientation".</p>	<p>Intends to create a pooled fund combining public and private sector funds, all from Brazil. Also involves interesting use of market forces (commercial value of veterinary-use) to subsidize/offset costs for the human-use market and sustainably finance a "humanitarian vaccine for Schistosomiasis".</p>	<p>Clearly outlines aim to involve developing countries vaccine manufacturers networks, technical partners (STPH), industry, as well as endemic countries. Emphasis placed on South-South partnerships on solidarity basis as opposed to the altruistic non-commercial model. Fiocruz is a WHO Collaborating Center for Global Health and South-South Collaboration and thus has the resources and mandate to see this carried out</p>	<p>Will clearly build capacity in endemic countries. Will engage with LMIC manufacturers.</p>
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DEMONSTRATION PROJECT PROPOSAL - WITHDRAWN
August 2014

<p>+1. Dengue vaccine development</p> <p>Health Systems Research Institute (HSRI), Thailand, et al.</p> <p>Submitted via SEARO</p>	<p>Managed and funded by public government institutions but no explicit policies or principles for ensuring delinkage.</p>	<p>Collaboration between 3 universities and 3 government institutions; standard use of IP (even if actions of rights holders ensure access).</p>	<p>Strategies may include non-exclusive licensing and other practices to ensure access; not clear on how specifically access will be secured although the project does not aim at financial returns.</p>	<p>Grant-based funding but will utilize funding from Thailand government, which is fully supportive of the project.</p>	<p>Only discusses coordination within the consortium. However, as stated above, there is potential for misunderstanding the scope of the question as posed.</p>	<p>No clear details on how capacity will be built outside the involved institutions and outside Thailand.</p>
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¹ Dr Chamas did not evaluate or re-evaluate this proposal for reasons of conflict.