

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

# 7+1 DEMONSTRATION PROJECTS IDENTIFIED BY THE GLOBAL TECHNICAL CONSULTATIVE MEETING ON HEALTH R&D DEMONSTRATION PROJECTS

## Examination of addendum responses to innovation questions<sup>1</sup>

10 March 2014

Project	Delinkage	Open knowledge innovation	Licensing for access	Financing mechanisms	Coordination mechanisms	Capacity-building
<b>1. The Visceral Leishmaniasis (VL) Global R&amp;D &amp; Access Initiative</b>  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.
<b>2. Multiplexed Point-of-Care test for acute febrile illness</b>  Translational Health Science and Technology Institute (THSTI), India, et al.  Submitted via SEARO	States that public funding will ensure delinkage. However, there is a lack of specific information and evidence on how this will be achieved.	Uses PDP model. Knowledge sharing and use of IP pooling within the consortium but no wider access (details on sharing with external actors unclear).	Non-exclusive licensing to private actors in both developed and developing countries; low end price to be achieved through negotiation. This could result in competitive prices, but conversely, restriction to geographic markets can curtail competition. No explicit criteria provided in relation to affordability.	Traditional non-innovative grant based financing; mentions pooled funding, but does not document how this will be carried out. Seeks funding from developing countries.	No clear engagement of the wider community; details clearer with respect to specific partners' involvement.	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.
<b>3. Demonstration of the potential of a single dose malaria cure of artemether-lumefantrine through reformulation in a nano-based drug delivery system</b>  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.	Traditional mechanisms utilized; no clear method for open access and no open knowledge approach.	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.	Classic consortium proposal; relies upon grants from existing funders. Funding from BRICS to be sought and, if possible, pooled funding.	Only describes the coordination mechanism within the consortium. Project may act as a catalyst to African governments but no clear policy laid out.	Inherently includes capacity building due to geographical area and institutions involved.

<sup>1</sup> As proposed and carried out by Dr John-Arne Røttingen and Dr Claudia Chamas (former Chair and Vice-Chair of CEWG, respectively) in line with Executive Board decision EB134(5). This assessment is based solely on interpretation of the information submitted via the original proposal and the addenda responses to six additional questions.

Project	Delinkage	Open knowledge innovation	Licensing for access	Financing mechanisms	Coordination mechanisms	Capacity-building
<p><b>4. Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty</b></p> <p>Medicines for Malaria Venture (MMV)</p> <p>Submitted via EURO</p>	<p>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&amp;D process that fulfill these criteria.</p>	<p>Open source approach to collaboration and knowledge sharing.</p>	<p>Utilizes public domain.</p>	<p>Traditional grant-based funding – although attempt will be made to try to spread out financing needs between the partners involved.</p>	<p>Use of selection committee to select and prioritize profile of the pathogen box, thus involving and linking multiple stakeholders and avoiding duplication of work.</p>	<p>Universally available to any interested researcher. Partners in LMICs in South America, Africa and Asia.</p>
<p><b>5. 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 poverty<sup>2</sup></b></p> <p>Oswaldo Cruz Foundation (Fiocruz), et al.</p> <p>Submitted via AMRO</p>	<p>States that public funding and corporate social responsibility will ensure delinkage. However, there is a lack of specific information and evidence on how this will be achieved.</p>	<p>Not open knowledge innovation; IP protected within a PPP.</p>	<p>Utilizes positive access clauses in licensing agreements but will be an exclusive license.</p>	<p>Traditional grant-based funding. However, the proponents are clear on their desire to mobilize new developing country funders.</p>	<p>No clear or specific description provided of a wider coordination mechanism.</p>	<p>Will clearly build capacity in endemic countries. Will engage with LMIC manufacturers.</p>
<p><b>6. Development of Class D CpG ODN (D35) as an Adjunct to Chemotherapy for cutaneous leishmaniasis and Post Kala-Azar Dermal Leishmaniasis (PKDL)</b></p> <p>United States Food and Drug Administration (US FDA), et al.</p> <p>Submitted via AMRO</p>	<p>Clear on delinkage: No royalties to be applied to public sector institutions or institutions using public sector funds; will not attempt to recover R&amp;D cost.</p>	<p>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.</p>	<p>Equitable and humanitarian licensing approach.</p>	<p>Traditional grant-based funding. Focus on leveraging of funds from new actors and key States and institutions through collaboration with WHO.</p>	<p>WHO-based consortium including endemic countries and other key Member States and actors in the fields of CL and PKDL.</p>	<p>Manufacturing platform easily transferrable; expects to choose manufacturing sites in endemic countries and engage actively with LMIC manufacturers.</p>

<sup>2</sup> Dr Chamas did not evaluate this proposal for reasons of conflict.

Project	Delinkage	Open knowledge innovation	Licensing for access	Financing mechanisms	Coordination mechanisms	Capacity-building
<b>7. Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases</b>  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.
<b>+1. Dengue vaccine development</b>  Health Systems Research Institute (HSRI), Thailand, et al.  Submitted via SEARO	Managed and funded by public government institutions but no explicit policies or principles for ensuring delinkage.	Collaboration between 3 universities and 3 government institutions; standard use of IP (even if actions of rights holders ensure access).	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.	Grant-based funding but will utilize funding from Thailand government, which is fully supportive of the project.	Only discusses coordination within the consortium. However, as stated above, there is potential for misunderstanding the scope of the question as posed.	No clear details on how capacity will be built outside the involved institutions and outside Thailand.