Meetings of Stakeholders for Selected Health R&D Demonstration Projects

7 – 10 May 2014
World Health Organization, Geneva

CONCEPT NOTE

1. Introduction

The following four selected demonstration projects, and the stakeholder meetings, are linked to the World Health Assembly (WHA) resolution 66.22 and are part of a “strategic workplan” adopted by the resolution in “Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination”.


2. 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), Osaka University, et al. 8th May 2014, Thursday.


4. Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases - African Network for Drugs and Diagnostics Innovation (ANDI), China Tropical Diseases Drugs and Diagnostics Innovation Network (China NDI), et al. 10th May 2014, Saturday.

These projects have been selected after multiple rounds of assessment by experts at both regional and global levels. Each of these projects aim to address R&D gaps for needed health technologies in developing countries – but most importantly, their objective is to demonstrate, in view of market failure, alternative innovative ways of financing and coordinating R&D.

This series of stakeholder meetings have been designed to offer insight into these demonstration projects and to facilitate cooperation and support among existing and potential partners and donors.
2. **Background**

- 2010, WHA63.28, established the Consultative Expert Working Group on R&D: Financing and Coordination (CEWG).²
- 2012, WHA65.12, welcomed the analysis of the CEWG report and agreed on conducting consultations at various levels to discuss the CEWG report.
- 2012, 26-28 November, global open-ended meeting of Member States, a draft resolution was negotiated to follow-up on CEWG report and a strategic work-plan was agreed.
- 2013, May, WHA66.22,³ adopted the resolution as such that was agreed between the Member States in November 2012 open-ended meeting. Among other items the resolution requested the WHO Director-General to facilitate through regional consultations and broad engagement of relevant stakeholders the implementation of a few health research and development demonstration projects to address identified gaps that disproportionately affect developing countries, particularly the poor, and for which immediate action can be taken.
- 2013, June/July: 6 WHO regional offices issued calls for submission of proposals for projects.
- 2013, November: WHO regional offices shortlisted 22 projects for consideration.
- 2013, 3-4 December 3-4: A global technical consultative meeting of experts identified 7+1 proposals that have the potential to be demonstration projects.⁴
- 2013, 5 December: Member States requested additional information from the proponents on the innovative aspects of the 7+1 proposals.
- 2014, January: The 134th WHO Executive Board adopted decision EB134(5), identifying next steps – examination of the additional information and convening of stakeholder meetings. The decision also requested the Secretariat to identify indicators to measure success in this process.⁵
- 2014, 10 March: As per EB134(5), the former Chair and Vice-Chair of the CEWG, examined the additional information received and identified 4 projects that are ready for implementation.⁶
- 2014, 7 – 10 May: Stakeholder meetings for the four selected demonstration projects

3. **Objectives of the Stakeholders Meetings**

1. Bring together the stakeholders of the projects including existing and potential partners and donors.
2. Introduce the project, including technical details and the innovative aspects it would demonstrate.
3. Discuss project plans in terms of next steps, resource needs and responsibilities.
4. Continue to mobilize political and financial support for the project.

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⁴ [http://www.who.int/phi/implementat...phi_cewg_meeting/en/](http://www.who.int/phi/implementat...phi_cewg_meeting/en/)
⁶ [http://www.who.int/phi/implementation/10_March_2014_exam_add_info_results.pdf?ua=1](http://www.who.int/phi/implementation/10_March_2014_exam_add_info_results.pdf?ua=1)
4. **Expected Outcomes**
   - Stakeholders fully updated on the projects.
   - Project plans are discussed and finalized shortly after the meetings.
   - Identification of potential financing sources and mechanisms.
   - Identification of next steps for implementation.
Meeting of Stakeholders for the “Visceral Leishmaniasis Global R&D and Access Initiative” Demonstration Project

7 May 2014

WHO Headquarters, Geneva
Salle D

AGENDA

9:00-9:30 Registration

9:30-10:10 Welcome address and Setting the Context

- Dr Marie-Paule Kieny, Assistant Director-General for Health Systems and Innovation, WHO
- Dr Bernard Pécoul, Executive Director, DNDi
- Dr Zafar Mirza, Coordinator of the Department of Public Health, Innovation and Intellectual Property, WHO
- Q&A

10:10-11:00 SESSION 1 – The Visceral Leishmaniasis (VL) Global R&D and Access Initiative Demonstration Project

Overall presentation of the VL Global R&D and Access Initiative - VL Holistic approach

Chair: Dr John Reeder, Director, TDR

- Speaker – Dr Jorge Alvar, Head of Visceral Leishmaniasis Program, DNDi
- Speaker – Alexandra Heumber, Head of Policy Affairs, DNDi
- Q&A

11:00-11:15 Coffee

11:15-12:15 SESSION 2 – Towards Open Source: More Collaborative, Pre-Competitive and Sharing Resources

Panel discussion with reference to:

- Enhance the identification of new compounds from lead optimization to preclinical phase: the NTD Drug Discovery Booster Consortium (Objective 1 Activity 1)
- Development of a shared, open-access data base to identify determinants of treatment effectiveness (Objective 4)

Chair: Robert Don, Director of Drug Discovery and Preclinical Research, DNDi

- Speaker: Piero Olliaro, Team Leader, TDR
Speaker: Lluis Ballell, Director External, Tres Cantos Medicines Open Lab Foundation, GSK, Opportunities Diseases of the Developing World
Speaker: Charles Mombay, Head of Drug Discovery, DNDi
Speaker: Dr Philippe Guerin, Executive Director, WWARN
Respondent: Richard Bergstrom, Director General of EFPIA, Member of the governing board of Innovative Medicines Initiative
Q&A


Presentation of the study on Pool funding and voluntary contribution commissioned by DNDi

Chair: Professor Albrecht Jahn, Professor of Public Health, University of Heidelberg, Germany, Member of the CEWG

- Speaker: Suerie Moon MPA, PhD, Harvard School of Public Health Project Co-Director
- Q&A

13:15-14:00 Lunch Break

14:00-15:00 SESSION 4 – De-Linkage of the Price of the Product from the Cost of the R&D: Concretely, what does this mean in terms of access to treatment?

Panel discussion with reference to:
- Toward “gold standard” licensing terms (Moving an NCE from pre-clinical phase to POC) (VL 2098) (Objective 1 Activity 2); (Completing clinical development of existing candidates up to registration) (fexinidazole) (Objective 1 Activity 3)
- Incentive mechanism: Prize (Development of diagnostic technology to evaluate the role in transmission of asymptomatic careers and PKDL patients (Objective 2)

Chair: Jean-Francois Alesandrini, Director Advocacy & Fundraising, DNDI

- Speaker: Bénédict Blayney, Director Neglected Tropical Diseases, Sanofi
- Speaker: Jean-Pierre Paccaud, Director Business development, DNDi
- Speaker: Dr Jorge Bermudez, Vice-President of Health Production and Innovation, Fundação Oswaldo Cruz, (Fiocruz) Ministry of Health (Brazil)
- Respondent: Dr Manica Balasegaram, Director, MSF Access Campaign
- Q&A

15:00-16:00 SESSION 5 – Strengthening Cross-Regional Coordination And Capacity Building

Panel discussion with reference to:
- Critical role of endemic countries leadership (Development of PKDL treatment (Objective 3))
Challenges of developing and registering clinical trials in remote areas and strengthening and harmonization of regulatory mechanisms to meet essential standards

Chair: Dr Monique Wasunna, Director, Drugs for Neglected Diseases Initiative (DNDi), Africa Regional Office and Chief Research Officer and Assistant Director Research, KEMRI

Speaker: Dr Ahmed Mudawi Musa, Ph D Director of Institute of Endemic Diseases, Head of Department of Clinical Pathology & Immunology MoH Sudan, LEAP member

Speaker: Dr Dinesh Mondal, Senior Scientist, International Centre for Diarrhoeal Disease Research, Bangladesh (ICCDR B)

Speaker: Dr Shyam Sundar, Professor of Medicine, Institute of Medical Sciences, Banaras Hindu University, India

Speaker: Dr Carlos M. Morel, Director, National Institute of Science and Technology for Innovation in Neglected Diseases (INCT-IDN), Centre for Technological Development in Health (CDTS), Oswaldo Cruz Foundation (Fiocruz)

Speaker: Dr Nathalie Strub-Wourgaft, Medical Director, DNDi

Respondent: Mr Ole Olesen, Director of North-North Cooperation, European & Developing Countries Clinical Trials Partnership (EDCTP)

Q&A

16:00-16:15 Coffee

16:15-17:15 Wrap-up and next steps

This session focuses on the practical next steps: the project plan, milestones and mobilization of resources necessary to deliver the proposal.

This session gives also Member States an opportunity to ask any unanswered questions and to raise any necessary points for discussion.

- Jean-Francois Alesandrini, Director of Advocacy and Fundraising, Alexandra Heumber, Head of Policy Affairs, Jorge Alvar, Head of VL program, DNDi
- Dr Zafar Mirza, WHO
- Question time and discussion (Opportunity for further questions and discussion points from the floor)

17:15-17:30 Closing remark by Dr Bernard Pécul, DNDi
Meeting of Stakeholders for the “Development of Class D CpG ODN as an Adjunct to Chemotherapy for Cutaneous Leishmaniasis and Post Kala-Azar Dermal Leishmaniasis” Demonstration Project

8 May 2014

WHO Headquarters, Geneva
Salle D

AGENDA

8:30-9:00  Registration

9:00-9:30 Welcome address and Setting the Context

- Dr Marie-Paule Kieny, Assistant Director-General for Health Systems and Innovation, WHO
- Dr Daniela Vertheyli, Office of Biotechnology Products, Center for Drug Evaluation and Research, USFDA
- Dr Zafar Mirza, WHO/PHI

9:30-10:30 Session 1: CL & PKDL Global Situation

Chair: Dr Bernard Pecoul, DNDi

- Overview on the Global situation of CL – Daniel Argaw, MD. Medical Officer, Leishmaniasis Control Programme, Neglected Tropical Diseases Control Department, WHO
- Challenges in the treatment of CL. – Byron Arana, MD, PhD. Head, CL Program, DNDi
- Overview on the epidemiology and immunology of PKDL - Professor Ed Zijlstra, FRCP FRCPath PhD; Rotterdam Centre for Tropical Medicine/ Senior Consultant DNDi
- Treatment modalities for PKDL - Dr. Ahmed Mudawi Musa, MBBS, DTM & H, DLSHTM, MSc TM & IH, Ph D Director, Institute of Endemic Diseases, University of Khartoum; Associate Professor, Head, Department of Clinical Pathology & Immunology
- Q&A

10:30-10:45 Coffee

10:45-12:15 Session 2 – Innate Immune Modulators for the Treatment of CL and PKDL: Innovative Scientific Approach and Technical Feasibility

Chair: Dr Ahmed Mudawi Musa, Ph D Director of Institute of Endemic Diseases, Head of Department of Clinical Pathology & Immunology MoH Sudan, LEAP member

- Innate Immune Modulators in the therapy for CL and PKDL - Byron Arana. MD, PhD. Head, CL Program, DNDi
- Q&A

12:15-13:00 SESSION 3 – Technical Feasibility and De-Linkage of the Price of the Product from the Cost of the R&D: An New Model

**Chair:** Dr Analía Porras, WHO-AMRO

- Manufacturing, Preclinical and Clinical experience with CpG ODN for Malaria) Ken Ishii M.D. Ph.D. National Institute of Biomedical Innovation (NIBIO); WPI Immunology Frontier Research Center (IFREC), Osaka University
- Outline of the intellectual property and available practices that will be used to ensure the effective use of equitable or humanitarian licensing as a means to improve global access to essential products by ensuring affordability of the final product. Daniela Verthelyi, M.D. Ph.D.

13:00-14:00 Discussion and conclusions: Implementation and next steps
Meeting of Stakeholders for the “Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty” Demonstration Project

9 May 2014

WHO Headquarters, Geneva
Salle D

AGENDA

9.00-9.30 Registration

9.30-10.30 Welcome address and Setting the Context

This session will give introductory comments that explain the context for the CEWG Demonstration Projects emphasizing their significance and importance for public health, as well as MMV and its proposal “Exploiting the Pathogen Box: an international Open Source collaboration to accelerate drug development in addressing diseases of poverty”.

- WHO: Dr Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation
- MMV: Andrea Lucard, Executive Vice President, External Relations
- WHO: Dr Zafar Mirza, Coordinator of the Department of Public Health, Innovation and Intellectual Property

10.30-11.15 SESSION 1 “Exploiting the Pathogen Box” - Implementation and innovation

This session explains the origin and impact of MMV Open Access Malaria Box and the more recent Pathogen Box which frame the subsequent discussions on the proposal. The full details of the proposal are then covered with a focus on implementation and innovation.

Chair: Dr John Reeder, Director, TDR

- Dr Tim Wells, CSO (MMV) – Setting the scene: background and proposal objectives
- Dr Jeremy Burrows, Head of Discovery (MMV) – Proposal summary
- Dr Paul Willis, Director, Discovery (MMV) – Proposal details including implementation, partners, open source collaboration, innovation and governance

11.15-11.30 Coffee

11.30-12.30 SESSION 2 “Exploiting the Pathogen Box” - Implementation case studies

This session illustrates, with historical case studies, successful examples which have been developed from the MMV Malaria box and, thus, illustrate how new projects could be initiated and followed up out of “Exploiting the Pathogen box”.

Chair: Dr Piero Olliaro, TDR
- Dr Jenny Keiser (STPH) – New Schistosomiasis series
- Dr Jean-Robert Isset (DNi) – New Kinetoplastid series
- Question time and discussion on proposal (Panel of all speakers from Sessions 1 & 2)

12.30-13.30 Lunch Break

13.30-14.30 SESSION 3 “Exploiting the Pathogen Box” - Resource mobilization

This session focuses on the practical next steps: the project plan, milestones and mobilization of resources necessary to deliver the proposal.

Chair: Neil McCarthy, Director External Relations (MMV)

- Dr Paul Willis (MMV) – Next steps including: status, milestones for first 2 years, detailed project plans
- Dr Richard Gordon (South African MRC) – Leveraging resources: statement of requirements and existing contributions
- Question time and discussion on resource mobilisation

14.30-14.45 Coffee

14.45-15.45 SESSION 4 “Open Discussion – Member States”

This session gives Member States an opportunity to ask any unanswered questions and to raise any necessary points for discussion.

Chairs: Dr Zafar Mirza (WHO) and Neil McCarthy (MMV)

- Question time and discussion (Panel of all speakers. Opportunity for further questions and discussion points from the floor)

15.45-16:00 SESSION 5 “Concluding remarks”

- Andrea Lucard, Executive Vice President, External Relations, MMV
- Dr Zafar Mirza, WHO/PHI
Meeting of Stakeholders for the “Development of Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases” Demonstration Project

10 May 2014

WHO Headquarters, Geneva
Salle D

AGENDA

8:30-9:00  Registration

9:00-9:30  Welcome address and short remarks

- Dr Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation, WHO
- Dr Tshinko Ilunga, Vice Chair of ANDI Board
- Mr Bamidele Ilebani, UNOPS/ANDI, Head of UNOPS Office, Ethiopia
- Dr Zafar Mirza, WHO/PHI

9:30-10:50  SESSION 1 – Project overview: Development of easy to use and affordable biomarkers as diagnostics for types II and III diseases

This session will provide an overview of the Diagnostics project based on the three integrated platforms that will be used to implement the project. The three platforms are:

i. Platform for screening, development and evaluation.
ii. Platform for Access - covering manufacture, regulatory, procurement and integration of with e/m health.
iii. Platform for networking among partners and others, supported with databases for open knowledge sharing/exchange. This platform will cover cross cutting issues linked to the project such as tech transfer initiatives, IP management and capacity building linked to the project as core cross cutting issues.

Chair/Moderator: Dr John Reeder, Director, TDR

- Speaker: Dr Solomon Nwaka (Ag Director of ANDI) will introduce the project, partners and outline the project plan
- Speaker: Dr Wei Hu/Dr Ting Zhang (NIPD, China CDC) will present the screening, development and evaluation platform with proposed activities
- Speaker: Dr Peter Chun (EASE-Medtrend)/Dr James Kimotho (KEMRI) will present the access platform with proposed activities
- Speaker: Dr Kathy Tietje (PATH)/Dr Solomon Nwaka will present the networking platform with proposed activities
- Q&A

10:50-11:10  Coffee
**11:10-11:50  SESSION 2 – Panel discussion focusing on specific inputs to strengthen the project**

- *What is missing in the project plan and platform areas, partnership and financing opportunities.*

**Chair/Moderator:** Dr Xiao-Nong Zhou, National Institute of Parasitic Diseases, China CDC

- Panelist: Dr Solomon Mpoke, Director KEMRI, Kenya
- Panelist: Dr Ralph Schneideman, PATH Seattle
- Panelist: Dr Charles Mgome, Executive Director, EDCTP
- Panelist: Dr Jennifer Dent, BVGH Seattle
- Panelist: Dr Karniyus Gamaniel, Director General, NIPRD, Nigeria

**11:50-12:30  SESSION 3 – Panel discussions focusing on cross-regional coordination, capacity building and technology transfer within the project**

- *Critical role of endemic countries leadership*
- *Overcoming challenges of development, manufacture and registration in developing countries*

**Chair/Moderator:** Dr Feng Zhou, African Development Bank

- Panelist: Dr Richard Gordon, Director-SHI, South African MRC (TBC)
- Panelist: Ms EunJu kim, SD Diagnostics
- Panelist: Dr Catharina Boehme, CEO FIND (TBC)
- Panelist: Dr Carel ijesselmuiden, Executive Director, COHRED (TBC)
- Panelist: Dr Irena Prat, WHO/EMP, Geneva Switzerland
- Panelist: Dr Welington Oyibo, University of Lagos, Nigeria
- Panelist: Dr Xiao-Nong Zhou, NIPD, CDC China

**12:30-13:30  Final outline of the project plan and conclusions**

- Speaker: Dr Solomon Mpoke, Director, KEMRI, Kenya
- Wrap-up and next steps (WHO, ANDI)