

# Report of the WHO Strategic and Technical Advisory Group for Neglected Tropical Diseases

Salle C, WHO headquarters, Geneva, Switzerland  
12–13 April 2011



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A meeting of the Strategic and Technical Advisory Group for Neglected Tropical Diseases (STAG-NTD) was held at the headquarters of the World Health Organization (WHO) in Geneva, Switzerland, on 12–13 April 2011. The list of participating members, observers and secretariat is attached (Annex 1), as well as the agenda (Annex 2).

The Chairman, Professor David Crompton, opened the meeting by welcoming the new members of the STAG. WHO's Assistant Director-General for HIV/AIDS, tuberculosis, malaria and neglected tropical diseases, Dr Hiro Nakatani, spoke on behalf of the Director-General, Dr Margaret Chan, and welcomed the participants. Thanking Professor Sir Roy Anderson for having chaired the STAG for the past four years, Dr Nakatani introduced Professor Crompton as its new Chairman, and emphasized the importance of building on WHO's first global report on neglected tropical diseases, which was launched in 2010. The Chairman, in his message, expressed his desire to focus on the draft roadmap for implementing the report, particularly on setting targets for important milestones.

## 1. Report from the Director of WHO/NTD

Dr Lorenzo Savioli (Director, WHO's Department of Control of Neglected Tropical Diseases) summarized progress, achievements and challenges in control of NTDs. Progress was made in the following areas in 2010:

- dracunculiasis eradication;
- preventive chemotherapy, especially increases in global coverage for schistosomiasis, soil-transmitted helminthiasis, lymphatic filariasis, onchocerciasis and trachoma;
- innovative and intensified disease management for the leishmaniasis and trypanosomiasis;
- vector ecology and management, particularly prevention and control of dengue;
- neglected zoonotic diseases, notably elimination of dog rabies in Latin America;
- capacity-building.

Actions taken following the recommendations of the STAG meeting held in 2010 included procurement of praziquantel for schistosomiasis control; zoonotic diseases; monitoring and evaluation; and drug efficacy. Dr Savioli explained the purpose of the roadmap, which is to implement the policies and strategies set out in the *Global Plan to Combat Neglected Tropical Diseases 2008–2015* (published in 2007) and the *First WHO Report on Neglected Tropical Diseases* in 2010.

Recalling all the partnerships between WHO and the private sector for NTD drug donations, Dr Savioli emphasized the need for strengthened public sector capacity to optimize such donations. Challenges facing the NTD community include access to treatments, especially praziquantel, benznidazole, and anti-leishmaniasis medicines, especially liposomal amphotericin B.

Dr Savioli announced that the Global Health Council has offered to host a joint meeting with WHO of global NTD partners in 2012.

The Chairman and participants congratulated Dr Savioli and the NTD Department on their achievements during the past year.

## 2. Report from the Working Group on Monitoring Drug Efficacy

Professor Mamoun Homeida, Chairman of the Working Group, presented a summary report of its second meeting held on 22–23 February 2011. This group now has four subgroups working on benzimidazoles, ivermectin, praziquantel and medicines for kinetoplastids, respectively.

**Subgroup on benzimidazoles.** The subgroup has developed a standardized protocol to assess the efficacy of benzimidazoles in the field based on two efficacy studies: a multi-centre study carried out in several countries, as well as another in Ethiopia.

**Subgroup on ivermectin.** A standard operating procedure has been developed for collection and preservation of microfilaria samples for inclusion in the sample repository and potential genotypic examination. A study in Mali and Senegal has shown the possibility of eliminating onchocerciasis infection and interrupting transmission of the disease. An epidemiological evaluation of the effect of community-directed treatment with ivermectin on *Onchocerca volvulus* infection has been performed in 18 sites; the prevalence of infection was compared with that predicted by the ONCHOSIM computer simulation model for villages with the same duration of treatment and the same pre-control endemicity levels. ONCHOSIM can be used to alert control managers and, where the prevalence is not responding as expected, drug efficacy should be evaluated. A similar model could be useful for other diseases such as lymphatic filariasis, schistosomiasis and soil-transmitted helminthiasis. Ongoing research on other medicines including moxidectin was summarized.

**Subgroup on praziquantel.** Monitoring and evaluation of parasite population genetics has been carried out in several African and Asian countries, and a genetic approach to identifying *Schistosoma mansoni* drug-resistance genes has been developed. The *S. mansoni* and *S. japonicum* genomes have been sequenced and biomarkers identified for oxamniquine resistance. Phenotypic assays of praziquantel's efficacy have also been developed.

**Subgroup on medicines for kinetoplastids.** The Working Group noted that controlled distribution of donated medicines for the trypanosomiasis has tightened regulations and facilitated monitoring. Although it may be difficult, it would be desirable to introduce an analogous system for leishmaniasis.

Maintaining high efficacy and effectiveness of NTD medicines is key to expanding interventions in both preventive chemotherapy and intensified case management. STAG acknowledges the progress made by the Working Group and its various subgroups.

*STAG recommends that future work should focus on incorporating drug efficacy monitoring in field interventions by building technical expertise and laboratory networks.*

## 3. Report from the Working Group on Access to Quality-Assured Essential Medicines

Professor Nilanthi de Silva, Chairman of the Working Group, presented a summary report of the activities undertaken by members.

The Global NGO Deworming Inventory web site was launched by Children Without Worms in 2010. Data from 24 NGOs that included deworming for soil-transmitted helminthiasis in 2009 suggest that 62.9 million school-aged children were treated by NGOs in 2010 and that a significant proportion (20.8 million) were not captured by WHO's PCT Databank.

The subgroup on access to praziquantel has estimated the projected annual need for praziquantel in 2011–2015, and the availability of donor funding and in-kind donations. Despite joint planning of national requirements, coordinated drug procurement and consensus on quality assurance policy for drug procurement, a shortfall of 50 million tablets is foreseen.

In a study of the quality of selected medicines for NTDs, a significant proportion of samples from South-East Asian and West African countries tested in WHO prequalified laboratories in Hanoi (Viet Nam) and Rabat (Morocco) failed to conform with requirements in USP32 monographs. Almost all problems concerned albendazole and mebendazole. The sources of failing samples fall into two groups: (i) locally manufactured products with no significant international projection outside the countries surveyed; (ii) products procured by some NGOs through procurement agents and supplied without national regulatory oversight of the authorities in recipient countries.

Inaccurate or incomplete product information leaflets were also found, with discrepancies between information provided for the same product in the same country. Chewable tablets were found to have contradictory statements: “chew before swallowing” versus “can be chewed”.

Based on the findings of the survey, the Secretariat has drafted a manual containing practical advice for drug regulatory authorities.

The Secretariat has developed a similar manual for national programme managers on the prevention, detection and management of serious adverse events. Countries will need to adapt this manual to their local needs. The United Republic of Tanzania has already done so, and the manual will be field tested during the MDA scheduled for April 2011.

The Working Group noted the many issues relating to medicines for NTDs for which no preventive chemotherapy interventions are available (e.g. Buruli ulcer, leishmaniasis, trypanosomiasis, yaws).

STAG endorses *continuation of the Global NGO Deworming Inventory*, and encourages NGOs to participate in the inventory and communicate their results to WHO focal points and ministries of health.

STAG recommends continued coordination by WHO of praziquantel supplies and maintenance of consensus on quality standards, and *enhanced advocacy by WHO for Merck KGaA to increase its annual donation*.

STAG recommends *further sampling and testing of medicines for NTDs* with special focus on donated albendazole and mebendazole; *revision of WHO’s International Pharmacopoeia* with regard to dissolution rate test requirements for chewable tablets of albendazole and mebendazole; provision of feedback to NGOs regarding the need for quality assurance in drug procurements through the NGO Deworming Inventory web site.

STAG *endorses the manual on assuring safety of preventive chemotherapy interventions* for the control of NTDs and recommends that WHO engages in strong promotion of the manual in pharmacovigilance training courses; raised awareness among NTD control programme managers and drug regulatory authorities; and inclusion of management of severe adverse events on the basis of the safety manual in national action plans.

STAG also recommends that WHO considers *including one new member with expertise in NTDs with no PCT interventions in Management Unit*, and establishing a new subgroup to identify the main problems with regard to access to quality assured medicines for such diseases and possible solutions.

#### **4. Report from the Working Group on Monitoring and Evaluation (M&E) of Preventive Chemotherapy Interventions**

Dr Engels, Coordinator of WHO/NTD Preventive Chemotherapy and Transmission Control, presented the summary report of the Working Group on behalf of its Chairman, Dr Zaramba. The presentation focused on discussions during two meetings held in 2011: the Working Group on M&E, and the meeting of NTD regional officers and data managers.

The working group now has three subgroups: M&E of national programmes; monitoring of disease-specific indicators; and measuring enhanced outcomes and impact.

**Subgroup on M&E of national programmes.** A regional M&E framework has been drafted for WHO’s Regional Office for Africa for all NTDs; a standardized template for multi-year national action plans (Master Plans for all NTDs) has been developed; a macro-planning tool – the Funding Gap Analysis Tool – has been developed by USAID/RTI and adopted by WHO; a Joint Reporting Form is now available; the use of mobile phone technology has been successfully tested for transmission of preventive chemotherapy data and reporting (mHealth); harmonized mapping guidelines have been developed by WHO-APOC; and databases maintained by WHO headquarters and regional offices have been harmonized with those maintained by the regional offices for Africa and for the Americas.

The subgroup’s work plan for 2011 and beyond includes reporting of coverage as part of sector-wide indicators of national health services, as recommended by the STAG in 2010; developing annual micro-planning tools (e.g. data flow and quality assessment tools); building capacity, especially at the district level, with training-of-trainers modules; developing a methodology and framework for evaluation and/or review of NTD programmes; and designing advocacy and resource mobilization kits.

**Subgroup on monitoring of disease-specific indicators.** The subgroup has revised guidelines on monitoring and epidemiological assessment of mass drug administration (MDA) in the Global Programme to Eliminate Lymphatic Filariasis. The number of countries requiring MDA has reduced from 81 to 72. A proposal for guidance on the distribution of albendazole and mebendazole after 6 years of distribution in school-based deworming programmes or after stopping MDA for lymphatic filariasis has been discussed, and draft guidelines are in preparation.

An informal consultation on the use of diagnostic tools to guide and certify disease elimination was held in July 2010. The issues discussed at this meeting included the development of novel tests in view of future diagnostic needs of control and elimination programmes using preventive chemotherapy; infection versus transmission markers; antigen versus antibody tests; and the possibility of a “multiplex”-type package of tests to evaluate the impact of such programmes.

**Subgroup on measuring enhanced outcomes and impact.** The subgroup has identified key constituencies that needed to be represented on the Working Group and approached members from appropriate organizations. It has developed a strategy for the collection and collation of existing data on enhanced outcomes and impact indicators of preventive chemotherapy interventions. A number of students at Imperial College London and Emory University (Atlanta, USA) are working on literature reviews, which will be available by mid-2011. On the basis of the promised reviews, the Working Group plans to identify an appropriate set of measurable impact indicators and assess the feasibility of collecting such impact data in ongoing preventive chemotherapy interventions. It will constitute a multisectoral task force to design a data collection package to document the impact of ongoing large-scale preventive chemotherapy programmes as needed by specific stakeholders to underpin NTD control policy and/or advocacy, and explore funding opportunities for such impact evaluation.

STAG recognizes the *package of programmatic and M&E tools* jointly developed by WHO and NTD partners as current best practice; recommends that WHO formally adopts this package to roll out preventive chemotherapy interventions; and operationalizes M&E tools in a regional context.

STAG recognizes the efforts of the Working Group on M&E to issue *guidance on stopping or modifying interventions in an evolving epidemiological situation* and endorses the proposed guidelines for stopping LF MDA, including the re-assessment of nine countries as not needing MDA for LF; and the proposed control strategies for soil-transmitted helminthiasis in this respect, the latter as interim guidelines until more evidence is gathered from the field.

STAG agreed to *include representatives of disease specific technical groups* in the Working Group in order to favour information exchange, consensus-building and consistent information flow to national programmes.

## **5. Accelerating work to overcome the global impact of NTDs: a roadmap for implementing the first global report on NTDs**

The draft roadmap was reviewed in detail by STAG. Members made helpful contributions about the structure and text of the document, which were included in the revised version recommended for presentation to the Director-General of WHO. The targets and milestones for implementation of the roadmap were also discussed extensively and endorsed by STAG.

## **6. Summary report of the Working Group and STAG deliberations**

The reports of the Working Groups were presented in summary to the representatives of the partner organizations who joined the STAG.

## **7. Presentation of the roadmap**

Relevant sections of the revised roadmap, including final targets and milestones, were shared with partners and revised to reflect their feedback.

Colleagues from partner organizations strongly endorsed the importance of the work carried out by WHO's Department of Control of NTDs, and all present declared their support for its continuation.

## **8. Final recommendations (not in order of priority)**

1. The roadmap for implementing the first WHO report on NTDs was endorsed, subject to minor editorial and textual revision, and recommended for presentation to WHO's Director-General. Two versions should be made available: the first, to be finalized shortly, for WHO's internal use; the other version, for external use especially by partner organizations, will be finalized later.
2. Dengue epidemic prone countries should build capacity and efforts must be coordinated at regional and global level in order to stem the spread of possible outbreaks by cross border exchange of information and effective surveillance (cases and vectors). The STAG advises that WHO/NTD should coordinate dengue prevention and control activities within WHO and support efforts at regional and country levels.
3. WHO should continue to work with the Global Health Council to convene a second global NTD partners meeting in 2012.
4. WHO should establish a new Working Group on Integrated Control of Zoonotic NTDs in the context of veterinary public health to assist STAG. The Working Group should be chaired by Professor Malika Kachani.
5. Future work on monitoring drug efficacy and safety should focus on incorporating drug efficacy monitoring in field interventions by building expertise and creating laboratory networks.
6. WHO should advocate for improved access to benznidazole for Chagas disease and liposomal amphotericin B for the leishmaniases.
7. WHO should be encouraged to expand its prequalification activities to essential NTD medicines.
8. The Global NGO Deworming Inventory should be continued and more NGOs encouraged to participate and communicate their results to WHO focal points in countries and ministries of health.
9. WHO should continue to coordinate the global supply of praziquantel, maintain consensus on quality standards, and engage in enhanced advocacy for Merck KGaA to increase its annual donation.
10. Sampling and testing of essential medicines for NTDs should be continued, and national drug regulatory authorities and NGOs made aware of the need for quality assurance in procuring such medicines.
11. STAG-NTD endorses the manual on assuring safety of preventive chemotherapy interventions for the control of NTDs and recommends final publication and strong promotion by WHO.
12. WHO should include one new member with expertise in NTDs for which no preventive chemotherapy interventions are available in the Management Unit of the Working Group on Access to Assured-Quality Essential Medicines.
13. STAG-NTD recommends that WHO adopts the package of programmatic and M&E tools jointly developed by WHO and NTD partners for preventive chemotherapy interventions and regional distribution.
14. STAG-NTD endorses current WHO guidance on stopping or modify interventions in an evolving epidemiological situation and the proposed guidelines for stopping LF MDA, including the re-assessment of nine countries as not needing MDA for LF. The control strategies for soil-transmitted helminthiasis proposed by the M&E Working Group should be used as interim guidelines until more evidence is available.
15. The M&E Working Group should include representatives of disease-specific technical groups to enhance information exchange, consensus building and consistent information flow to national programmes.

**List of Participants****MEMBERS**

- \* **CICOGNA, Dr Francesco**  
Senior Medical Officer, Directorate General for the European Union and International Relations, Ministry of Health of Italy, via Giogia Ribotta, 5, Rome 00144, Italy  
Tel: 39 (0)65994277; E-mail: f.cicogna@sanita.it
- CROMPTON, Professor David (Chair)**  
University of Glasgow, Glasgow, Scotland  
Mailing address: Melrose cottage, Tyndrum, Perthshire FK 20 8SA, Scotland, United Kingdom of Great Britain and Northern Ireland  
Tel: +44 1838400203; E-mail: dwtc@tyndrum.demon.co.uk
- DE SILVA, Professor Nilanthi (Rapporteur)**  
Professor of parasitology, Faculty of Medicine, University of Kelaniya, P.O. Box 6, Talagolla Road, Ragama, Sri Lanka  
Tel: +94 11 2911143; E-mail: nrdesilva@gmail.com
- DIAS, Dr João Carlos Pinto**  
Senior Researcher, FIOCRUZ, Fundação Oswaldo Cruz, Centro de Pesquisas René Rachou, Laboratório de Triatomíneos e Epidemiologia da Doença de Chagas, Av. Augusto de Lima, 1715 Barro Preto - Belo Horizonte 30190002 MG - Brazil  
Tel: 55 (0) 31 329 53566; Fax: 55(0) 31 3295 3115; E-mail: jcpdias@cpqrr.fiocruz.br
- EBERHARD, Dr Mark**  
Director, Division of Parasitic Diseases, Centers for Disease Control and Prevention, 4770 Bufford Highway NE, 30341 - Atlanta, GA, USA  
Tel.: +1 (770) 488-7791; Fax: +1 (770) 488-7794; E-mail: mle1@cdc.gov
- ENDO, Dr Hiroyoshi**  
Professor and Chair, Department of International Affairs and Tropical Medicine, Tokyo Women's Medical University, School of Medicine, Tokyo, Japan  
Tel: 81 46 873 4108; E-mail: endo-hiroyoshi@w2.dion.ne.jp
- FENWICK, Prof. Alan**  
Director, Schistosomiasis Control Initiative, Department of Infectious Disease Epidemiology, Imperial College, St Mary's Hospital, Norfolk Place, London W2 1PG - United Kingdom  
Tel: +44 207 594 3418; Fax: +44 207 262 8140; E-mail: a.fenwick@imperial.ac.uk
- GANGULY, Prof. Nirmal K.**  
Distinguished Biotechnology Professor and Advisor Transnational Health Science and Technology Institute, National Institute of Immunology, New Delhi 110067; New Delhi 110029, India - E-mail: nkganguly@nii.ac.in
- GOTUZZO, Dr Eduardo**  
Director, Instituto de Medicina Tropical, Alexander von Humboldt, Universidad Peruana Cayetano Heredia, Peru  
Tel: 511-4823910, 4823903, Fax: 511-4823404, Mobile:511- 999007028  
E-mail: eduardo.gotuzzo@upch.pe
- GYAPONG, Prof. John O.**  
Director, Research and Development Division, Ghana Health Service, PO Box MB-190, Accra, Ghana  
Tel: +233 21 681085; Fax: +233 21 226739; E-mail: John.Gyapong@ghsmail.org or gyapong@4u.com.gh

**HOLMES, Professor Peter**

Former Vice Principal for Research and Territorial Vice-Principal for Biomedicine, University of Glasgow.  
Home address: 2 Barclay Drive, Helensburgh, G84 9Rd, Scotland.  
Tel: 44 1413303836; E-mail: p.holmes@admin.gla.ac.uk

**HOMEIDA, Prof. Mamoun Mohamed Ali**

Professor of Medicine & Therapeutics and President of the University of Medical Sciences & Technology, El  
Riyad, 12810 Khartoum, Sudan  
Tel: 249 183224762; E-mail: homeidam@umst-edu.org

\* **HOPKINS, Professor Donald R.**  
Vice President, Health Programs, The Carter Center, One Copenhill, 453 Freedom Parkway, Atlanta, GA 30307,  
United States of America (AMRO)  
Tel:+1 (404) 420-5100 /(800) 550-3560; E-mail: carterweb@emory.edu

**KACHANI, Professor Malika DVM PhD**

Professor of Parasitology, College of Veterinary Medicine, Western University of Health Sciences, 309 E.  
Second Street, Pomona, California USA 91766-1854,  
Tel: 1 909 469 5302; Fax: 1 909 469 5635; E-mail: mkachani@westernu.edu

**KOURÍ FLORES, Prof. R. Gustavo**

Instituto de Medicina Tropical "Pedro Kouri" (IPK), Autopista novia del Mediodia Km6 172, Municipio Lisa,  
P.O. Box 601, Marianao 13, Ciudad de la Habana – Cuba, E-mail: gkouri@ipk.sld.cu

**MALECELA, Dr Mwelecele Ntuli**

Director of Research, National Institute for Medical Research, P.O. Box 9653, Dar-es-salaam Ocean Road,  
Luthuli Street, Dar es Salaam - Republic of Tanzania  
Tel: +255 22 2121400/2125084; Fax: +255 22 2121360; E-mail: mmalecela@hotmail.com

**MAS COMA, Prof. Honoris Causa Santiago**

Director, Departamento de Parasitología, Facultad de Farmacia, Universidad de Valencia, Avenue Vicent  
Andres Estelles s/n , 46100 Burjassot, Valencia, Spain  
Tel: 34 96 354 49 05 or 34 96 354 4298; Fax: 34 96 354 47 69; E-mail: S.Mas.Coma@uv.es

**ROSENBERG, Dr Ronald**

Division of Vector Borne Disease, Centers for Disease Control and Prevention, Rampart Road, Fort Collins,  
Colorado 80521, United States of America. Tel: +1.970.221.6407; E-mail: rosenberg@cdc.gov

**SADRIZADEH, Dr Bijan**

Academy of Medical Sciences, No. 67, West Jamali Alley, Vafamanesh Street, Passdaran Avenue, Tehran - Iran  
(Islamic Republic of)  
Tel: +98 21 2293 0390 or 2293 2554; Fax: +98 21 2293 2125; E-mail: sadrizadehb@ams.ac.ir

**SHEPARD, Dr Donald Sloane**

Donald S. Shepard, Ph.D., Professor, Heller School 275, MS035, 415 South Street, Brandeis University,  
Waltham, MA 02454-9110 USA  
E-mail: shepard@brandeis.edu; Web: [www.brandeis.edu/~shepard](http://www.brandeis.edu/~shepard)  
Tel: +1-781-736-3975; Fax: +1-888-429-2672

**ZARAMBA, Dr Samuel**

Director, Health Services, Curative & Community, Ministry of Health, P.O. Box 825, Kampala, Uganda  
Tel.: +256-414-340873, +Fax 256-414-340881; E-mail: mmmbahemuka@yahoo.com;  
zarambasam@yahoo.co.uk

**ZHOU, Dr Xiao-Nong**

Deputy Director, National Institute of Parasitic Disease, Chinese Center for Disease Control and Prevention  
(China CDC), 207 Rui Jin Er Road, Shanghai 200025, People's Republic of China  
Tel: 86 21 64738058; Fax: 86 21 64332670; Email: ipdzhouxn@sh163.net

\* unable to attend

## **WHO Regions**

**AFRO - Dr A. Onyeze, NTD Programme Manager**

**EMRO - Dr R. Ben Ismail, Regional Adviser, DCD/TCD**

## **WHO Secretariat**

Dr H. Nakatani, ADG, HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases (HTM)

Dr L. Savioli, Director, Control of Neglected Tropical Diseases (NTD)

Dr D. Daumerie, Programme Manager, NTD

Dr D. Engels, Coordinator, Preventive Chemotherapy and Transmission Control, NTD

Dr J. Jannin, Coordinator, Innovative and Intensified Disease Management, NTD

Dr F. Meslin, Neglected Zoonotic Diseases, NTD

Dr F. Rio, Capacity Building, NTD

Dr R. Velayudhan, Vector Ecology and Management, NTD

Ms L. Aimé-McDonald, Assistant - Ms C. Suchet, Programme Assistant, NTD

Dr A. Alwan, ADG, Noncommunicable Diseases and Mental Health (NMH)

Dr N. Banatvala, Senior Adviser, NMH

Dr S. Mariotti, Prevention of Blindness & Deafness, Chronic Diseases and Health Promotion, NMH

Dr R. Ridley, Director, Special Programme for Research and Training in Trop. Diseases (TDR)

Dr P. Olliaro, Leader, Chemotherapy for Helminths and other NTDs, TDR

**4<sup>th</sup> Meeting of the Strategic and Technical Advisory Group on  
Neglected Tropical Diseases (STAG-NTD)  
12-13 April 2011  
WHO/HQ, Geneva  
Salle C**

**Agenda**

**Tuesday, 12 April 2011 - STAG members and secretariat only**

<b>Time</b>	<b>Session</b>	
9:00	<b>Welcome, introductions and adoption of the agenda</b>	ADG/HTM/NTD and DWT Crompton Chair STAG
9:15	<b>Report from NTD Director on status, progress and achievements with NTD control</b>	L. Savioli, WHO
10:00	<b>Working Group on monitoring of anthelmintic drug efficacy</b> Report of the second meeting	M. Homeida Chair WG
<b>10:30</b>	<b><i>Coffee/tea break</i></b>	
11:00	<b>Working Group on access to assured-quality essential medicines for NTD</b> Report of the third meeting	N. de Silva Chair WG
11:30	<b>Working Group on monitoring and evaluation of preventive chemotherapy interventions</b> Report of the second meeting	S. Zaramba, Chair WG
<b>12:30</b>	<b><i>Lunch</i></b>	
13:30	<b>Accelerating the work to overcome the global impact of NTDs. A roadmap for discussion</b>	Chair STAG
<b>16:00</b>	<b><i>Coffee/tea break</i></b>	
16:30	Discussion of the roadmap (continued)	Chair STAG
<b>18:00</b>	<b><i>Cocktail (invitation extended to partners)</i></b>	

**Wednesday, 13 April 2011 (STAG Members and partners)**  
**Salle C**

<b>Time</b>	<b>Session</b>	
9:00	<b>Revised roadmap and main recommendations of the STAG.</b> Presentation and discussion	Chair STAG
<b>10:30</b>	<b><i>Coffee/tea break – joined by partners</i></b>	
10:45	<b>Summary report of the Working Groups and STAG deliberations.</b> Discussion and comments from partners	Chairs of Working groups
11:45	<b>Presentation of the roadmap</b> Discussion and comments from the partners	Chair STAG
<b>12:30</b>	<b><i>Lunch break</i></b>	
13:30	<b>Presentation of the roadmap <i>and recommendations</i></b> Discussion and comments from the partners (continued)	Rapporteur STAG
15:30	<b>Closure of the meeting and coffee/tea break</b>	