

National Tuberculosis Encounter—Brazil July 17-28, 2006: Trip Report

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Strategic Objective SO5 TB

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

Management Science for Health's Rational Pharmaceutical Management Plus (RPM Plus) Program traveled to Brazil to co-facilitate the Second National Tuberculosis Encounter including South-to-South sessions with international partners from Stop TB, South Africa Medical Research Council and Global TB Alliance/South Africa. Purpose of the visit to Brazil was also to monitor on-going activities and to strategize future work with its partners the Professor Hélio Fraga TB Reference Center and the National Institute for Quality Assurance.

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Key Words

Tuberculosis, TB, MDR-TB, FDC, Stakeholders, Quality Assurance

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ACRONYMS

CRPHF	Professor Hélio Fraga TB Reference Center
Farmanguinhos	Drug production arm of Fiocruz
Fiocruz	National Research Center for Developing Drugs, Biologicals and Related Supplies
FDC	Fixed dose combination drug products
INCQS	Brazilian National Quality Assurance Institute
MoH	Ministry of Health
MSH	Management Sciences for Health
MDR-TB	Multi-drug resistant tuberculosis
NTP	National Tuberculosis Control Program
QA	Quality Assurance
RPM Plus	Rational Pharmaceutical Management Plus Program
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

In 2003 USAID mission initiated support for the *Professor Hélio Fraga TB Reference Center* (CRPHF). The CRPHF was mandated by the Ministry of Health (MOH) as the center for controlling the quality of TB diagnostics and treatment in the government's national health system (*Sistema Única de Saúde or SUS*). Overall, CRPHF is responsible for developing, analyzing and transferring technologies to combat TB in the country and to monitor the approximately 2,000 cases of multi-drug resistant TB (MDR-TB).

Since February 2004 the USAID mission has funded RPM Plus to support CRPHF by providing technical assistance in TB pharmaceutical management. All RPM Plus activities are in varying stages of implementation in collaboration with CRPHF using local and international TB experts.

Purpose of Trip

The Second National Conference of the TB Network took place in São Paulo, Brazil on 19-22 July, 2006. RPM Plus sponsored participation of National and International Experts on subjects related to the RPM Plus activities underway in Brazil such as development of Fixed Dose Combination (FDC) tuberculosis drugs, update regimens for treatment of re-treatment cases, quality assurance for TB drug products and monitoring the diagnosis and treatment of MDR-TB patients. The event also allowed the beginning of a South-to-South collaboration between Brazil, South Africa and India.

RPM Plus/Brazil manager, Thomas Moore also traveled to Rio de Janeiro to review status of on-going RPM Plus activities with local staff and consultants and plan strategies for reaching the objectives for the activities this year. The activity was funded as follows: Three of the international South-to-South participants including Thomas Moore were covered by RPM Plus/TB core funds. The other international experts traveled on their own funding. RPM Plus/Brazil funds were used for some of the related local costs.

Scope of Work

Scope of work for Thomas Moore is as follows:

1. Coordinate parallel session on development of FDC TB products in Brazil
2. Present in plenary on RPM Plus activities in Brazil and how they relate to International TB goals of the Stop TB partnership
3. Support conference presentations and round table discussions of the following:
 - a. Dr. Richard Chaisson, Johns-Hopkins University, USA—speaking in two sessions: (1) update on clinical research in TB and (2) the international vision of state of the art of clinical research development in tuberculosis contributing to one of the RPM Plus activities

- b. Dr. Bernard Fourie, MRC, South Africa –speaking in two sessions: (1) state of the art of FDCs in the world and (1) Introduction of medicines in Fixed Dose Combinations: Experience in South Africa one of the RPM Plus activities
 - c. Dr. Martino Laurenzi, TB Global Alliance speaking in two sessions: (1) Perspective of the New Drugs in Development and (2) Panorama of New Drug Development by the TB Global Alliance
 - d. Dr. Ernesto Jaramillo, WHO, Geneva, Green Light Committee—speaking in two sessions: (1) Priorities in the Production of Medicines for MDR-TB and (2) Initiatives for the Control of TBMDR in the World
 - e. Dr. Joel Keravec, RPM Plus, Brazil—speaking on quality control of anti-tuberculosis medicines in Brazil one of the RPM Plus activities and coordinating one of the parallel sessions on actual situation in Brazil and perspectives of producing TB medicines
 - f. Dr. Miguel Aiub Hijjar, Centro Helio Fraga—speaking on epidemiologic surveillance and control of MDR-TB one of the RPM Plus activities
 - g. Dr. Margreth Dalcolmo, Centro Helio Fraga—speaking on current situation and perspectives of the treatment of MDR-TB one of the RPM Plus activities
 - h. Dr. Andre Daher, National Institute of Quality—speaking on perspectives of the new drugs development in Brazil including FDCs
 - i. Eight local manufacturer representatives—speaking on production capacity, TB products registered, principal challenges, problems with raw materials acquisition and quality
4. Meet with RPM Plus staff, consultants and partners
5. Brief/debrief USAID officials in person or electronically as requested

ACTIVITIES

The Second National Tuberculosis Encounter took place in São Paulo, Brazil from 19-22 July, 2006. Participants consisted of practicing pulmonologists, the national TB Network, the academic community doing research in the area of TB, NGOs, national TB program partners, National Society of Pulmonologists and Tisiologists (TB clinicians), the national TB program, the Ministry of Health Department of Pharmacy Assistance, TB pharmaceutical manufacturers, National Institutes in Quality Assurance, National Reference Center Professor Helio Fraga, international partners for TB. In all approximately 500 persons were in attendance.

The information presented in this trip report are direct activities involving RPM Plus/Brazil and international consultants. See Annex 1 for the complete program in Portuguese language and Annex 2 the program translated into English.

1. Coordinate parallel session on development of FDC TB products in Brazil

There were two round table discussions on issues related to development of TB drugs.

- a. The first was entitled: *Actual Situation in Brazil and Perspectives of Producing TB Medicines*. This session was led by Joel Keravec, RPM Plus/Brazil Coordinator and João Batista Oliveira, Ministry of Health Pharmacy Department.

Representatives from eight Brazilian manufacturing laboratories made presentations on their manufacturing capacity, which TB drugs they are currently producing or that are registered in Brazil for manufacture at their facilities and some of their production problems. In general all had the following in common:

- Have a much larger capacity to produce than is currently being done
- Are part of a network of facilities that have the first option for manufacture of medicines and supplies for the national government including the Ministry of Health
- Were not aware of the MoH program to change to the following drug products even though RPM Plus invited representatives to the stakeholder working group responsible for moving to these products: (1) three-drug FDC containing rifampicin, isoniazid and pyrazinamide (RHZ); (2) change all current capsule products to tablets; (3) prepare sachets for pediatric doses
- All but one have some development capacity and are currently developing products not interesting to the MoH; the other laboratory is Fiocruz which is one of the major MoH producers and has extensive development capacity and is aware of the MoH program of moving to the above products
- There are currently no raw materials producers in Brazil and all raw materials must be imported
- Biggest problem today is the receipt of good-quality raw materials for TB and other medicines (Law No. 8666/93 does not allow to pre-qualify the raw material manufacturers)

The eight laboratories presenting and their comments follow:

- 1) Laboratório Farmacêutico da Marinha—the laboratory of the Brazilian Navy:
 - has large capacity for liquids than is currently producing
 - can export to other countries if required
 - has functioned as a manufacturing laboratory for 100 years
 - supports the Navy hospitals and the MoH
 - is producing first and second line TB drugs

- 2) Laboratório Farmacêutico da Aeronáutica—the laboratory of the Brazilian Air Force:
 - can export to other countries if required
 - new lab facility opens in 2007 with large capacity, eg. 900 million capsule production daily
 - ethionamide is registered to be manufactured but never received a request from the MoH

- 3) Nuplan—the laboratory of Rio Grande do Norte State:
 - 1996 began production of TB medicines
 - are remodeling to manufacture TB medicines in a separate facility to prevent cross contamination of products
 - has capacity to produce 71 million tablets daily
 - are in a planning process for developing sachets and 4-drug FDC for the MoH

- 4) FURP—the laboratory of São Paulo State:
 - has capacity to produce 2.5 billion units of a product daily
 - problem with poor quality raw materials because of Law No. 8666/93 which prohibits the pre-qualification of raw material manufacturers
 - after a brief stop are starting to produce again the 2-drug FDC containing rifampicin and isoniazid (RH)

- 5) LAQFEX—the laboratory of the Brazilian Army:
 - worried that Brazilian laboratories are not always producing in a quality way
 - are doing bio-equivalence studies for the 3-FDC product
 - are demanding good raw materials which has not been happening and partly blames the Law No. 8666/93
 - requesting that a network of manufacturing laboratories be established to work on common problems and in developing the 3-FDC,4-FDC, and other products requested by the MoH

- 6) Iquego—the laboratory of Goiás State:
 - has capacity to produce ~93 million tablets per month
 - has capacity to produce ~113 million blisters per month
 - currently produce 2 million tablets per month
 - was producing the TB drugs, 2-FDC (RH) and the single drugs rifampicin (R), isoniazid (H), pyrazinamide (Z), and ethambutol (E) and stopped

- biggest problem is receipt of good quality raw materials
 - would like to qualify the raw material producers but are not allowed to do so by the Law No. 8666/93
 - have a separate area for production of RH to prevent cross contamination
 - when doing bio-equivalence testing of drugs have problem with costs of the reference materials and cost of testing methods
- 7) Lafepe—the laboratory of Pernambuco State:
- has capacity to produce 227 million capsules per year operating two shifts
 - can export to international market if required
 - current production is 1 billion units per year
 - has capacity to produce TB medicines, capsules and tablets, semi-solids (creams and ointments), injectables
 - has an area segregated for TB medicine production to prevent cross contamination
 - is developing the 3-drug FDC, RHZ but on a different strength than the one required by the PNT
 - has capacity to initiate new studies
 - biggest problems are with the Law No. 8666/93 preventing pre-qualifying raw materials suppliers and registering generic products with the Brazilian Anvisa drug regulatory authority
- 8) Farmanguinhos—federal laboratory located at Fiocruz Institute¹ in the State of Rio de Janeiro:
- presented by Dr. Andre Daher researcher
 - Fiocruz produces seven different TB product lines
 - is currently working on development of the 3-FDC and 4-FDC in collaboration with Brazil RPM Plus program as one of our activity stream line

Dr. João Batista Oliveira, Ministry of Health, Pharmacy Department reported the following information:

- last year the MoH created a network of producers, a type of coordination
- need to have a single formulation and package for government medicines
- trying to work with a local company to begin manufacture of raw materials
- need to harmonize the logistics of testing quality of raw materials
- there are 11 official laboratories including those from the military, States and Fiocruz (federal)

Dr André Gemal, director of the National Institute of Quality - INCQS moderated the discussion panel with Joel Keravec and proposed to organize technical visits by INCQS technicians to the facilities of network producers when methodology related problems were identified during the TB drug quality control program. He commented

¹ Fiocruz is a research complex where medicines, biologicals, and related supplies are developed, tested and released for manufacture and use by the Brazilian population. Farmanguinhos is the actual manufacturing arm for medicines at Fiocruz

on the current situation and difficulties regarding good quality availability of Rifampicin on the international market, and underlined the urgent need to set up a coordinated policy between the different producers of the Brazilian network to attend to the needs of the TB program.

Dr. Bernard Fourie presented on the experience of introducing FDCs in South Africa. Dr. Fourie helped WHO develop the 4-FDC which has become the standard for TB treatment worldwide. Dr. Fourie is a researcher working with the Medical Research Council of South Africa, consultant for WHO and other partners in TB product development, and researcher for the MEND/Global TB Alliance project in South Africa.

- It took almost 10 years to complete the development, introduction, training and use of FDCs in South Africa
- Today it is working well with good communication among manufacturers (mostly local, but some importation), health care providers both national and MoH, and patients
- Nine referral centers are set up where single drugs are kept in the advent of hypersensitivity reactions to the FDC products
- Bioequivalence testing in Brazil can be greatly consolidated so that each laboratory is not having to conduct the tests
- Dr. Fourie is interested in collaborating with Brazil manufacturers and the national TB program as it moves to use of FDCs
- Dr. Fourie recommends using the WHO regimen and formulations and showed evidence of why those dosages are more appropriate for a population than the one currently used by Brazil which has only two patient weight bands, over and under 50 kg

Thomas Moore representing Dr. Ernesto Jaramillo of the GLC/GDF of WHO who was unable to attend, presented on *Initiatives for Controlling MDR-TB in the World*. As representative of GDF/GLC, Thomas Moore expressed GLC/GDF willingness to set up future technical sessions to discuss how Brazilian manufacturers could enter the international market since there is a big shortage of quality producers of medicines for MDR-TB. Dr. Fourie suggested having the first such technical session in Geneva so that a wider array of WHO departments (MEDS-pre-qualification program, Stop TB, Infectious Diseases) could participate.

The conclusions and priorities for moving to FDCs of those attending the session were as follows:

- Lobby to change the Law No. 8666/93 in order to pre-qualify produces
- Without change in Law No. 8666/93 the quality assurance problems with raw materials will be difficult to resolve
- Make the network of producers work something like it did under an older network a decade ago called CEME (Central de Medicamentos) for raw materials and drugs procurement on a centralized model

- Seek assistance from WHO through GDF/GLC
- Seek assistance from South-to-South partners in South Africa, TB global alliance/South Africa and NIPER laboratories in India
- Establish a stakeholders working group including the network of producers mentioned above, Anvisa, Fiocruz, MoH pharmacy department, national quality institute (INCQS), national TB program, partners such as Management Sciences for Health
- Obtain consensus from the stakeholders working group on the six steps for introduction of FDCs provided by Dr. Bernard Fourie as follows:
 - (1) All National TB Program documentation should be revised to comply with the new mode of treatment, including the program manual, treatment guidelines, treatment cards, drug supply ordering forms, etc.
 - (2) Training based on the new program manual must be provided to program staff at all levels
 - (3) Before starting full-scale use of FDCs, a plan for consuming the existing stocks of loose tablets should be in place to avoid economic loss
 - (4) Even when FDC treatment is used, a small reserve stock of loose tablets should be available at central health facilities which handle cases of severe adverse events. Until more experience is gathered, it is suggested that approximately 5% of the total anti-TB drug stock should be in the form of single-drug formulation
 - (5) FDCs are recommended with the provision that only quality products should be used. Thus, obtaining quality products is an essential step in the implementation of FDC-based treatment. Although rifampicin bioavailability is of fundamental importance, it is recommended to procure only FDCs with proven bioavailability of all constituent drugs
 - (6) Whereas many programs will manage the procurement process independently, countries in the developing world have the opportunity to seek assistance in obtaining quality drugs, including 4-drug FDCs from the GDF. Experience with large-scale purchases through the GDF shows that quality 4-drug FDC-based treatment can be obtained for as little as, or less than, the price of treatment with the same drugs in the form of loose tablets

- b. The second session entitled: *TB Pharmaceutical Management and Actual Perspectives in Brazil* was led by Thomas Moore, RPM Plus/Brazil

The following sessions were presented and a question and answer session took place all in plenary:

- (1) Dr. Bernard Fourie, MRC, South Africa spoke on: *State of the Art of FDCs in the World* related to a RPM Plus/Brazil activity
- (2) Thomas Moore representing Dr. Ernesto Jaramillo, WHO, Geneva, Green Light Committee who was unable to attend presented on *Initiatives for the Control of TBMDR in the World*
- (3) Dr. Joel Keravec, RPM Plus, Brazil spoke on *Quality Control of Anti-tuberculosis Medicines in Brazil* one of the RPM Plus/Brazil activity

- (4) Dr. Miguel Aiub Hijjar, Centro Helio Fraga presented on *Epidemiologic Surveillance and Control of MDR-TB*, a RPM Plus/Brazil activity
 - (5) Dr. Margreth Dalcolmo, Centro Helio Fraga spoke on the *Current Situation and Perspectives of the Treatment of MDR-TB*, a RPM Plus/Brazil activity
 - (6) Dr. Andre Daher, National Institute of Quality spoke on *Perspectives of the New Drugs Development in Brazil including FDCs*, one of the RPM Plus/Brazil activities
2. Present in plenary on RPM Plus activities in Brazil and how they relate to International TB goals of the Stop TB partnership

Thomas Moore sat at the opening session director's table of the *Second National Conference of the TB Network* and spoke on the the RPM Plus/Brazil activities and how they are integrated with the priorities of the MoH, local partners CRPHF and INCQS, and Stop TB International TB goals

3. Support conference presentations and round table discussions of the following:
- a. Dr. Richard Chaisson, Johns-Hopkins University, USA—speaking in two sessions: (1) update on clinical research in TB and (2) the international vision of state of the art of clinical research development in tuberculosis

Dr. Chaisson presented data on work he is doing with local counterparts in Brazil which have shown good results for detecting new cases and getting good treatment compliance
 - b. Dr. Bernard Fourie, MRC, South Africa –speaking in two sessions: (1) state of the art of FDCs in the world and (1) Introduction of medicines in Fixed Dose Combinations: Experience in South Africa

See discussions in sections “a.” and “b.” above
 - c. Dr. Martino Laurenzi, TB Global Alliance speaking in two sessions: (1) Perspective of the New Drugs in Development and (2) Panorama of New Drug Development by the TB Global Alliance

Dr. Laurenzi represented the Global TB Alliance/South Africa to discuss how new drug development is going worldwide and how South African research organizations are playing a role. Dr. Laurenzi invited Brazilian researches to participate even more than is currently going on
 - d. Dr. Ernesto Jaramillo, WHO, Geneva, Green Light Committee—speaking in two sessions: (1) Priorities in the Production of Medicines for MDR-TB and (2) Initiatives for the Control of TBMDR in the World

Dr. Jaramillo could not attend and requested that Thomas Moore represent GLC/GDF with the slides he provided. Thomas Moore translated them into Portuguese and presented them in two different sessions of the conference agenda

- e. Dr. Joel Keravec, RPM Plus, Brazil—speaking on quality control of anti-tuberculosis medicines in Brazil one of the RPM Plus activities and coordinating one of the parallel sessions on actual situation in Brazil and perspectives of producing TB medicines

See discussions in sections “a.” and “b.” above

- f. Dr. Miguel Aiub Hijjar, Centro Helio Fraga—speaking on epidemiologic surveillance and control of MDR-TB one of the RPM Plus activities

Dr. Hijjar gave a brief background on how the Centro Helio Fraga developed as a center for TB tools research and presented the surveillance tool jointly developed with RPM Plus/Brazil and how it is working to decentralize proper diagnosis, care and drug management for MDR-TB patients throughout Brazil

- g. Dr. Margreth Dalcolmo, Centro Helio Fraga—speaking on current situation and perspectives of the treatment of MDR-TB one of the RPM Plus activities

Dr. Dalcolmo covered the clinical aspects of treatment how the new surveillance system jointly developed with RPM Plus/Brazil helps assure drugs are available when MDR-TB patients need them

- h. Dr. Andre Daher, Farmanguinhos/Fiocruz—speaking on perspectives of the new drugs development in Brazil including FDCs

See discussions in sections “a.” and “b.” above

- i. Eight local manufacturer representatives—speaking on production capacity, TB products registered, principal challenges, problems with raw materials acquisition and quality

See discussions in sections “a.” and “b.” above

In a meeting with Dr. Joseney Santos, Thomas Moore and Joel Keravec on 22 July 2006, RPM Plus was asked to support more of South-to-South collaboration. He discussed the upcoming meeting (August 21-23, 2006) in Capetown with representatives of Brazil, South Africa and India on specific future collaborative activities for controlling tuberculosis. Dr. Santos asked RPM Plus to help develop the scope of work for this meeting to include aspects of pharmaceutical management such as development and implementation of FDCs and modifying treatment regimens. RPM Plus was asked to attend the meeting and to support the travel of three persons from the National TB Program. RPM Plus promised to review planned activities and budgets to see if the monies earmarked for international consultancies for

South-to-South both within the SO5 TB and Brazil TB funds would be sufficient for this support.

4. Meet with RPM Plus staff, consultants and partners

Thomas Moore and Dr. Joel Keravec, RPM Plus Brazil coordinator of activities, met with Dr. Jorge Luiz da Rocha and Dr. Luiz Gustavo Valle Bastos RPM Plus consultants, Dr. Miguel Aiub Hijjar, Director of CRPHF to discuss remaining activities for FY05 and to identify appropriate activities for FY06. The Second National TB Conference in Brazil also presented a great opportunity for input from other RPM Plus partners regarding future workplan activities.

5. Brief/debrief USAID officials in person or electronically as requested RPM Plus briefed Patricia Paine of the USAID/Brazil Mission during the Brazilian National TB Encounter

Collaborators and Partners

- Joseney Santos, Director of National TB Program
- Miguel Hijjar, Director, Centro de Referência Professor Hélio Fraga
- Dr. Margareth Dalcolmo, Centro de Referência Professor Hélio Fraga
- Dr André Gemal, Director of National Institute for Quality - INCQS
- Other MOH National TB Control Program officials

NEXT STEPS

Immediate Follow-up Activities

1. MoH Department of Pharmacy Assistance and RPM Plus will develop a work plan based on the discussions during the round table with the Brazilian medicine producers
2. Facilitate collaboration with Dr. Fourie of South Africa on development of FDCs in Brazil when Brazil is ready for his technical assistance
3. A Brazilian delegation is going to Cape Town in August 2006 to further discuss South-to-South cooperation among the three countries Brazil, India and South Africa in the area of TB control. RPM Plus will work with the national TB program to help develop the scope of work so as to include technical assistance in use of FDCs in Brazil

Recommendations

RPM Plus has been requested to provide technical assistance to the Brazilian TB medicines working group to develop and implement a program for initiating use of the 3-drug and 4-drug FDC in Brazil's national TB program. RPM Plus recommends this to continue through the South-to-South cooperation that is upcoming among Brazil, South Africa and India. Technical assistance would include provision of international consultants such as Dr. Bernard Fourie developer of the 4-FDC for the WHO during the activity. Technical managerial assistance will likely be requested for RPM Plus/Brazil to manage activities of the TB medicines working group and to provide local technical assistance as required.

RPM Plus/Brazil will consider follow-on South-to-South activities in detail during workplan development for FY06.

Agreement or Understandings with Counterparts

RPM Plus was requested to provide support for travel to Cape Town for the August initial meeting of the South-to-South cooperation among Brazil, South Africa and India. RPM Plus promised to look at its current projected activities one of which is to provide international consultancies to determine if this is possible. The current RPM Plus/Brazil workplan budget and the core SO5 TB workplan will likely have sufficient funds to co-support the South-to-South activity taking place in August in Capetown.

Important Upcoming Activities or Benchmarks in Program

This Second National TB Conference was a benchmark in showing how integrated RPM Plus/Brazil activities continue to be with the national TB agenda. Both during and outside the formal sessions many discussions took place on RPM Plus/Brazil activities and how and when future accomplishments will take place.

ANNEX 2. AGENDA: II BRAZILIAN TUBERCULOSIS MEETING

July 19 to July 22, 2006

Centro de Convenções Pompéia

Av. Pompéia, 888 - São Paulo - SP

July, 19 - WEDNESDAY

7h00pm – 08h00pm – Opening ceremony - Brazilian Net of Research in Tuberculosis/REDE-TB, Brazilian Thoracic Association, Minister of Science and Technology and Partnerships.

08h00pm – 08h40pm - Conference - Evaluation on the Technological Competence for P&D&I of Immunology in Brazil: Are we Losing the Opportunity? - Dr. Célio Lopes of Silva

08h40pm – 9h40 - Cocktail

July, 20 – THURSDAY

Symposium: PUBLIC HEALTH IN BRAZIL - STATE OF THE ART.

Coordinating: Dr. Juan Stuardo Yazlle Rocha

08:00am - 08:20am - Politics of Health - Dr. Paulo Eduardo Mangeon Elias

08:20am - 08:40am - Economy and Health - Dra. Ana Luiza D' Ávila Viana

08:40am - 09:00am - Administration in Health - Dr. Eurivaldo Sampaio de Almeida

09:00am - 09:20am - Questions

Symposium: SOCIAL MOBILIZATION - BUILDING A COLLECTIVE ANSWER FOR THE CONTROL OF THE TUBERCULOSIS - Coordinating: Dr. Rodolfo Rodriguez Cruz (OPAS/MS)

09:20am - 09:35am - Carlos Basília (Rede TB/Fórum of ONGs TB-RJ)

09:35am - 09:50am - Dr. Jarbas Barbosa de S. Júnior (National Partnership of TB)

09:50am - 10:05am - Dr. Germano Gerhardt (SBPT)

10:05am - 10:20am - Dr. Ezio Távora (Research of Evaluation of the Actions of TB in Brazil)

10:20am - 10:40am - Questions

10:40am - 11:00am - Break

11:00am - 11:50am - Conference - Updating on Clinical Research - Dr. Richard E. Chaisson

11:50am - 12:15pm - Questions

12:15pm - 1:30pm - Lunch

1:15pm - 2:00pm - Visits to the Posters

Symposium: STATE OF the ART OF THE DEVELOPMENT OF CLINICAL RESEARCH IN TUBERCULOSIS - Coordinating: Dr. Marcus Barreto Conde

2:00pm - 2:20pm - International General Vision - Studies 27 and 28 CDC. - Dr. Richard E. Chaisson

2:20pm – 2:40pm - Priorities in the TB Net Research - Dr. Reynaldo Dietze

2:40pm - 3:00pm - Priorities of Ministry of Health in Clinical Research - Dr. Expedito Luna

3:00pm – 3:20pm - Questions

Symposium: UPDATING IN BASIC AREAS. - Coordinating: Neio Boechat

3:20pm - 3:40pm - Lines of Research in Immunopatology of TB in Brazil - Dr. Moisés Palaci

3:40pm - 4:00pm - Mechanisms of Patogenicity of the Mycobacterium tuberculosis - Dra. Vânia Bonato

4:00pm - 4:20pm - State of the Art of the Cellular Immunological Answer in TB - Dr. Esper Georges Kallás

4:20pm - 4:30pm - Questions

4:30pm - 4:40pm - Break

4:40pm - 4:30pm - Conference - Differences in Pathogenesis and in the Immune Answer Induced by Genotypes Different from Tuberculosis M. - Dr. Rogelio Hernandez Pando

5:30pm - 6:00pm - Questions

July, 21 - FRIDAY

Symposium: TUBERCULOSIS AND CO-INFECTION IN HIV - Coordinating: Dr. David Jamil Hadad

08:00am - 08:20am - Treatment of the Co-infection in TB/HIV and their Adverse Events - Dra. Valéria Cavalcante Rolla

08:20am - 08:40am - Revision of the Brazilian Guidelines 2006/MS/National Program of AIDS - Dr. Fábio Moherdau

08:40am - 09:00am – Clinical Exams and Treatment - Dr. Pedro Dornelles Picon

09:00am - 09:20am - Questions

Symposium: DIAGNOSIS - Coordinating: Dr. Clemax Couto Sant'anna

09:20am - 09:40am - State of the Art: Evaluation of New Diagnoses Methods of TB in Brazil - Dr. Afrânio Lineu Kritski

09:40am - 10:00am - Priorities of the National Net of Laboratories - Dra. Maria Cândida Dantas

10:00am - 10:20am – Tuberculosis Exams at the present time - Dr. Fernando Fiúza Mello

10:20am - 10:40am - Questions

10:40am - 11:00am - Break

11:00am - 11:50am - Conference - Evaluation of New phenotype methods in the Diagnosis of TB - Dr. Juan Carlos Palomini

11:50am - 12:15pm - Questions

12:15pm - 1:15pm - Lunch

1:15pm - 2:00pm - Visits to the Posters

Symposium: ADMINISTRATION OF MEDICINES AND CURRENT PERSPECTIVES - Coordinating: Dr. Thomas Moore

2:00pm - 2:20pm - Quality control of Pharmacos Anti-TB - Dr. Joel Keravec

2:20pm - 2:40pm - Epidemic Surveillance and Control of TBMR - Dr. Miguel Aiub Hijjar

2:40pm - 3:00pm-Current Situation and Perspectives of the Treatment of TBMR-Dra. Margareth Dalcolmo
3:00pm - 3:20pm - Perspectives in the Development of Association of Pharmacos in Fasten Dose Combined - Dr. Jorge Costa
3:20pm - 3:40pm-How the Mycobacterium tuberculosis became Resistant to Isoniazida-Dr. Diógenes Santos
3:40pm - 4:00pm - Perspective of the New Drugs in Development - Dr. Martino Laurenzi
4:00pm - 4:10pm - Questions
4:10pm - 4:20pm - Break
4:20p - 5:10pm - Conference - State of the Art of FDCs in the World - Dr. Bernard Fourier
5:10pm - 5:30pm - Questions

July, 22 - SATURDAY

Symposium: EPIDEMIOLOGY

Coordinating: Jamocyr Marinho

08:00am - 08:20am - Epidemiology of TB in Brazil - Dr. Joseney Santos

08:20am - 08:40am - State of the Art of the Epidemic Studies in Brazil - Dr. Antonio Ruf. in Netto

08:40am - 09:00am - Initiatives for the Control of TBMR in the World - Dr. Ernesto Jaramillo

09:00am - 09:20am - Questions

Symposium: OPERATIONAL STUDIES - Coordinating: Dr. Ricardo Ximenes

09:20am - 9:40am - State of the Art of the Operational Studies in Brazil - Dra.Tereza Cristina Scatena Villa

09:40am - 10:00am - DECIT - Priorities of Research of Brazilian Ministry of Health: TB foment - Dra. Suzanne Jacob Serruya

10:00am - 10:20am- Perspectives of Operational Researches in the State of São Paulo - Dra. Vera Galesi

10:20am - 10:40am - Questions

10:40am - 11:00am - Break

11:00am - 11:50am - Conference - New Drugs: Panorama of the TB Global Alliance Projects - Dr. Martino Laurenzi

11:50am - 12:15pm - Questions

12:15 - 1:15pm - Lunch

1:15pm - 2:00pm - Visits to the Posters

Symposium: TRAINING OF HUMAN RESOURCES

Coordinating: Dra. Valéria Maria Augusto

2:00pm - 2:20pm - Experience of the ICHORTA Project - Dr. José Roberto Lapa e Silva

2:20pm - 2:40pm - Priorities and Strategic Actions of Education in Health

2:40pm - 3:00pm – What the Specialist has to do in the Control of TB - Dr. Antônio Carlos Moreira Lemos

3:00pm - 3:20pm - Questions

Symposium: TRANSFER OF TECHNOLOGY

: Dr. Eduardo Bethlem

3:20pm - 3:40pm - Rede TB'S Experience in the Transfer of Technology - Dr. José Maciel Rodrigues Júnior

3:40pm - 4:00pm - Priorities in Tuberculosis to Brazil

4:00pm - 4:20pm - Priorities in Research of Neglectful Diseases (MCT)

4:20pm - 4:30pm - Questions

4:30pm - 4:40pm - Break

Table Round PERSPECTIVES OF NEW VACINAS Coordinating: Dra. Suzan Pereira

4:40pm - 5:00pm - Perspectives of Industrialization - Dr. José de R. Carneiro

5:00pm - 5:20pm - Perspectives of Latin America - Dr. Célio Lopes Silva

5:20pm - 5:40pm - Politics of Immunization in Brazil / MS / PNI - Dra. Antônia of Silva Teixeira

5:40pm - 6:00pm - Questions

6:00 - 6:30 - Closing of the meeting

Scientific commission

Afrânio Lineu Kritski - REDE TB - FM - UFRJ

Antônio Rufino Netto - FMRP - USP - REDE TB

Carlos Basília - Fórum ONG/TB-RJ

Célio Lopes Silva - FMRP - USP - REDE TB

Clemax Couto Sant'Anna - REDE TB - IPPMG - UFRJ

Diógenes Santos - PUC - RS - REDE TB

Fernando Fiúza of Melo - CATHEDRALS - SP

Jamocyr Marinho - UBM - SBPT

José Maciel Rodrigues Júnior - FMRP-USP - REDE TB

José Roberto Lapa e Silva - UFRJ - REDE TB

Josney Raimundo Santos - SVS-BAD

Margareth Pretti Dalcolmo - SBPT - CRPHF - BAD

Moisés Palaci - UFES - REDE TB

Pedro Picon - REDE TB - CATHEDRALS - RS

Reynaldo Dietze - UFES - REDE TB

Teresa Cristina Scatena Villa - REDE TB

Valéria Cavalcante Rolla - IEC - FIOCRUZ - REDE TB

Organizing commission

Afrânio Lineu Kritski - REDE TB - FM - UFRJ
Antônio Ruf. in Netto - FMRP - USP - REDE TB
Carlos Basília - Fórum ONG/TB - RJ
Célio Lopes Silva - FMRP - USP - REDE TB
Joseney Raimundo Santos - SVS - BAD
Marcus Barreto Conde - UFRJ - SBPT - REDE TB
Margareth Pretti Dalcolmo - SBPT - CRPHF - BAD
Mauro Zamboni - SBPT - INCA

Participant institutions

Brazilian Thoracic Association
General office of Surveillance to the Health - Ministry of Health
Center of Reference Professor Hélio Fraga - SVS/MS
General coordination of Endemic Diseases
Brazilian net of Research in TB / NET-TB
National coordination of DST / AIDS MS
Project MSH / Management Sciences for Health
Usaid / US Agency for International Development

Accomplishment and Organization

Brazilian net of Research in TB / Net - TB
Ministry of Health
Brazilian Thoracic Association

International Speakers

Bernard Fourier - British Medical Council - South Africa
Ernesto Jaramillo - TH/HIV and Drug Resistance - Stop TB Department - OMS
Juan Carlos Palomino - Institute of Tropical Diseases - Belgium
Martino Laurenzi - Global TB Alliance - USA
Richard E. Chaisson, M.D. - Teacher of Medicine, Epidemiology and Health
International - Johns Hopkins University
Rogelio Hernandez Pando - National Institute of Research of Mexico
Thomas Moore - Main Program Associate - Management Sciences goes Health - Rational
Pharmaceutical Program - USA
Viviana Ritacco - Bacteriologist - Buenos Aires - Argentina