FIFTH MEETING OF THE CORE GROUP OF THE GLOBAL DRUG-RESISTANT TB INITIATIVE (GDI)

8 July 2016

Geneva, Switzerland

WHO/UNAIDS building, Geneva

Global Drug-resistant TB Initiative

Accelerating the response

Table of Contents

Background

The Global Drug–resistant TB Initiative (GDI) has been constituted as a Working Group for drug-resistant TB related issues (DR-TB) replacing the previous MDR-TB Working Group and the global Green Light Committee (gGLC). The mission of the GDI is to serve as a multi-institutional, multi-disciplinary platform organizing and coordinating the efforts of stakeholders to assist countries build capacity for programmatic management of DR-TB (PMDT) in the public and private sectors. The ultimate aim is to ensure universal access to care and appropriate treatment for all DR-TB patients. The group will mobilize resources and undertake activities to ensure a holistic, quality-assured, patient-centred approach for all DR-TB patients within existing TB care structures as well as through innovative new partnerships in priority countries.

This was the fifth meeting of the GDI Core Group (CG), coordinated by the GDI secretariat housed in the Laboratories, Diagnostics and Drug Resistance (LDR) unit of the WHO's Global TB Programme (GTB). The meeting took place in WHO Headquarters in Geneva, Switzerland on 8 July 2016.

Meeting objectives

- To follow up on recommendations made and action points agreed upon during 4th GDI CG meeting in December 2015, and subsequent monthly teleconferences;
- To provide an update on progress in scale up of MDR-TB services and care, and updates on new policies;
- To provide an update on the progress of the respective GDI Task Forces; and
- To provide an update on the progress of the GDI "Costed Framework" document

Session 1: Update from the Secretariat

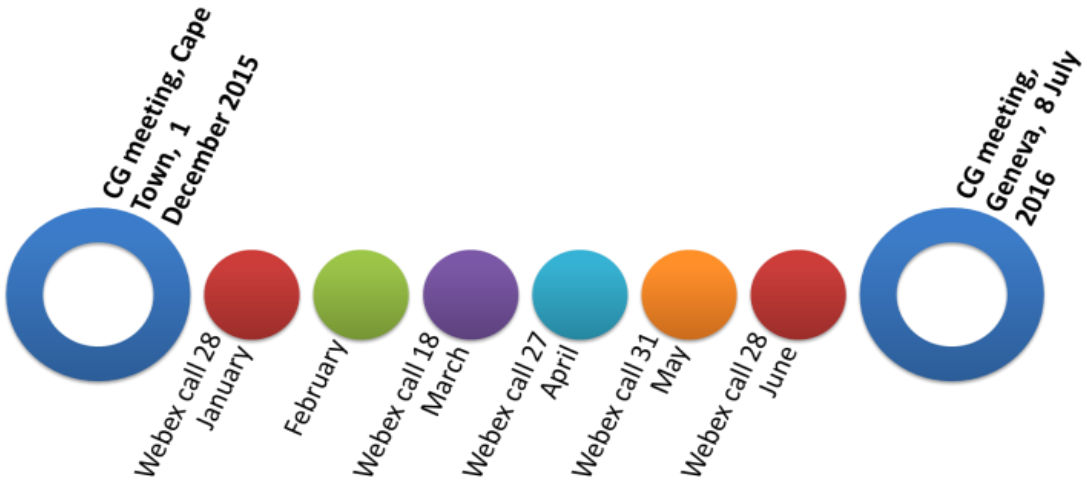
Meeting started with a foreword by the chair of the working group and introduction of all participants where several new core group members have introduced themselves (Subrat Mohanty, Rafael Laniado, Jacques van den Broek and Sarabjit Chadha).

On behalf of the GDI Secretariat, Fuad Mirzayev provided an update of the progress since the last in-person meeting in December 2015 in Cape Town, South Africa. The GDI core group had five webex-based online conference calls, current face-to-face meeting is group's first in 2016. Main developments were summarised:

- the core group has welcomed a new member in the Civil Society constituency – Mr Subrat Mohanty;
- the group has taken a firm decision to create a GDI-GLI Task Force and several core group members expressed interest to be part of it (Agnes Gebhard, Chen-Yuan Chiang, Carrie Tudor, Daniela Cirillo and Saira Khowaja);
- the series of experience sharing regional workshops on introduction of new DR-TB drugs has been completed with two workshops in 2016 for WPR and SEAR in Bangkok in February and for AMR in Panama city in April. A meeting of MDR-TB focal points from countries of EMR in Khartoum in May was also supported by the secretariat and the DR-TB STAT Task Force (previous workshops for EUR in Copenhagen September 2015 and for AFR and EMR in Nairobi in November 2015);
- Following a proposal prepared by the core group and the secretariat, new funding was received from the Stop TB Partnership;
- DR-TB STAT Task Force proposed a new work plan and budget, which was reviewed and subsequently accepted for funding;
- As decided by the core group, a consultant was hired and developed the draft "GDI Costed Framework" document.

The GDI Task Forces on Advocacy and Patient Centred Care have successfully accomplished their work plans and closed their activities. The DR-TB STAT Task Force has submitted the extended work plan, is funded and will remain active until the end of 2016. The DR-TB Research Task Force has just submitted the new work plan for the review and, if funded, will continue its activities during 2016.

An updated membership list of the core group was provided for information of all participants as well as a brief update of the current funding for activities.



Session 2: New WHO policy guidance

During this information session, on behalf of the WHO/GTB, Dennis Falzon and Alexei Korobitsyn presented latest updates of the WHO guidance on programmatic management of MDR-TB and second-line drug susceptibility testing. First presentation focused on the main novelties of the 2016 WHO guidelines that include recommendations on a shorter MDR-TB treatment regimen under specific conditions; reclassification of medicines used in the design of conventional MDR-TB treatment to reflect updates in the evidence on their effectiveness and safety; specific recommendations on the treatment of children with rifampicin-resistant or MDR-TB based on a first-ever individual patient data meta-analysis and the role of surgery in MDR-TB case management.

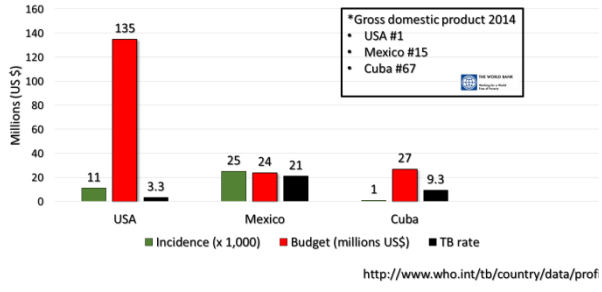
The presentation on WHO recommendations in the area of TB diagnostics provided updates on most recent policies and the use of the second line LPA for detection of resistance to fluoroquinolones and the second-line injectable anti-TB drugs.

More information is available at http://www.who.int/tb/areas-of-work/drug-resistant-tb/treatment/resources/en/

Session 3: MDR-TB scale-up in regions.

Updates from regional GLCs (rGLC), presented by respective rGLC chairs provided updates on the progress in regions since the meeting in Cape Town and also introduced a discussion on how GDI and rGLC can interact better. Chair rGLC AFRO, Hind Satti, could not participate in the meeting but presentation was made available to all meeting participants.

Tb incidence, TB program Budget and TB rate (2014)



http://www.who.int/tb/country/data/prof

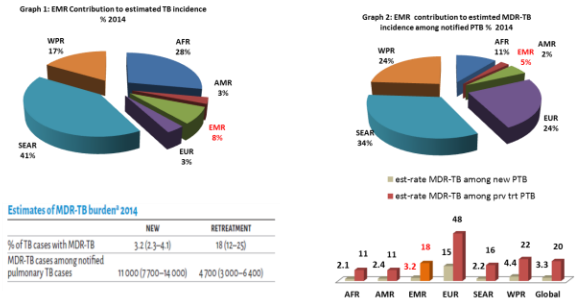
The **AMR rGLC** chair, Dr Rafael Laniado Laborin, has highlighted in his presentation that two countries (Brazil and Peru) account for more than half of the MDR-TB burden in the region. Many countries in AMR (53%) do not have access to the SL DST, which results in low proportion of estimated MDR-TB cases being treated. From patients identified though, the majority starts treatment (~90%). On average, MDR-TB and XDR-TB treatment outcomes are comparable to global statistics with significant proportion of patient being lost to follow up. While political commitment is evident for both TB and the DR-TB management, the investment in NTPs is highly variable and not always being appropriate to the needs. From observation of available data, the investment in TB is not a function of the countries' economic wealth, in other words some less affluent countries invest much more when compared per case of TB. Many countries in the region are transitioning from the GF funding and this presents an additional challenge for TB control in the near future. It was also noted that the rGLC having no sufficient political power may lead to inconsequential follow up of the recommendations by the national health authorities. High level advocacy and expansion of access to the new TB diagnostics and DST for SLDs were considered the most important areas for collaboration between rGLC and the GDI.

Chair of the **rGLC EMR** reported on some unique to the region challenges in TB and DR-TB management due to the multiple armed conflicts and political instability affecting number of countries in this region. While many countries in the region do not carry high

burdens of the MDR-TB, highest being in Pakistan, population movements and refugee crises are testing resilience of the health systems with many patients being lost at the brink between routine management and assistance in emergencies.

TB and MDR TB Burden in EMR 2014

EMR has 117 per 100,000 population as estimated TB incidence rate.
EMR is ranking 4 among other regions and is responsible about 8 % of estimated incident TB cases and 5% of MDR-TB cases incident globally. The estimated number of MDR-TB cases was 15900 in 2014

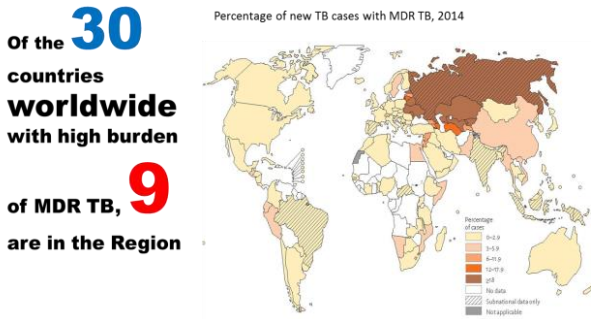


Estimates of MDR-TB burden[a] 2014

	NEW	RETREATMENT
% of TB cases with MDR-TB	3.2 (2.3–4.1)	18 (12–25)
MDR-TB cases among notified pulmonary TB cases	11 000 (7 700–14 000)	4 700 (3 000–6 400)

This also highlights the need for the rGLC in the region to tap into some unusual, external to TB areas of knowledge and expertise, involving specialists in complex emergencies and health systems in crisis, where GDI could possibly assist, given its broad, global reach and membership. Security situation in some countries often complicates and delays technical assistance and monitoring of TB programmes, also explaining plans for many regional trainings where rGLC actively contributes.

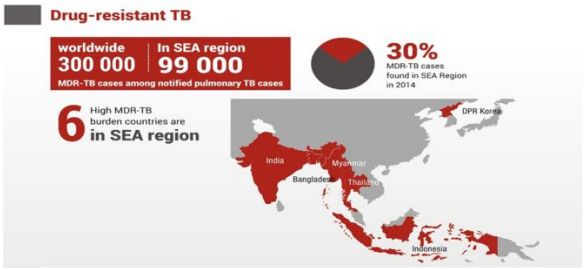
WHO European Region is the most affected area for MDR-TB in the entire world



Chair of **rGLC EUR** highlighted that EUR is the region with highest rates of MDR-TB globally. Countries have substantial experience in managing MDR-TB and are relatively well prepared in terms of TB and MDR-TB diagnostics. However, treatment outcomes greatly vary and default during treatment is generally high. The rGLC benefits from new platform of collaboration with ELI – European Laboratory Initiative. Another recent development, regional project funded by the GF - TB-REP, has entered into its initial phase of implementation with a scope that aims at supporting MDR-TB burden decrease, boosting political commitment and shift towards outpatient management models in 11 countries of the region.

Stronger collaboration needs with the GDI and other rGLCs were highlighted. Support and advice from the GDI on cautious introduction of shorter MDR-TB regimen was noted as a possible area for interaction.

rGLC chair SEAR - Sarabjit Chadha, has shared updates from the South-East Asia region that carries a significant proportion of the global burden of MDR-TB.



- **WHO estimation of MDR-TB: 2.2% (1.9-2.6) among new cases and 16% (14-18) among retreatment cases in SEAR (Globally 3.3% (2.2-4.4) among new and 20% (14-27)among retreatment cases)**
- **XDR–TB reported from 6 of the 11 Member States (105 countries globally by end of 2014)**

MDR-TB cases notification have been growing in recent years but number of patients notified is lagging behind (34%). The burden of MDR-TB may therefore be underestimated, also because of possible underrating of TB burden (example of recent prevalence survey in Indonesia). Support from the GDI may help to improve capacity of the rGLC in scoping the country needs and preparing plans, more updates and orientation session in the changing in the dynamically changing environment with new drugs, diagnostics and evolving recommendations, monitoring and

providing independent feedback on the performance of the rGLCs and facilitating links with partners and additional resources to assist implementation of new policies.

Jacques van den Broek, a new chair of **WPR rGLC** presented update of the activities since the beginning of 2016. The rGLC WPR holds monthly conference calls. The presentation has also provided plans developed by the rGLC to promote WHO recommendations, expand interaction with the NTPs and develop a system of sharing the reports and rGLC recommendations with countries and partners. The rGLC WPR has initiated a process to include a new member representing civil society and suggestions from the GDI and its CS constituency representative were appreciated. A suggestion to increase interaction between rGLC in different regions to share experiences was reiterated.

The session itself and discussions during this session clearly highlighted a need for stronger and more frequent interaction between the rGLCs and the GDI and it was agreed that a separate dedicated meeting needs to be planned to discuss concrete plans in relation to this need, a meeting that would include the GDI, the rGLC chairs and the secretariats. The CG has also raised and discussed an idea for the rGLCs to use some survey tools to collect a feedback from countries benefitting from the rGLC support.

Action points:

- To present the need and solicit from the Stop TB Partnership possible suggestions for a high level advocacy on importance of MDR-TB management in order to nurture and boost political commitment in affected countries.
- For rGLC chairs, to discuss with respective committees and regional secretariats their suggestions on possible avenues of interactions and support from the GDI to the rGLCs.
- To organise a dedicated meeting (potentially a conference call or a meeting in Liverpool during UNION conference) of GDI with the rGLCs and their secretariats and the GF to discuss a mechanism for expanded collaboration, platform for regular knowledge and experience sharing and clear assignment of roles and responsibilities.
- To develop a brief document (2-3 pager) following the meeting above that would clarify the roles and relationships of GDI and the rGLCs.

Session 4: GDI Task Forces

The **DR-TB Research Task Force** has submitted a new work plan that will be reviewed by the GDI chair and the secretariat and considered for funding.

Updates on the activities of the **DR-TB Task Force** were presented by Jennifer Furin. The group was funded for the new term until end of the year with renewed and expanded plan of activities. Complementary funding was also received from the MSF Access Campaign and the USAID. An update on the access and implementation of new anti-TB medicines has followed. During a discussion after DR-TB STAT presentation, the CG supported plans of the TF to document observations on the successful and unsuccessful models of new drugs introduction. The CG considered a need to perform a similar type of activities to support introduction of shorter MDR-TB regimen in countries. The CG has also noted that the DR-TB STAT TF leader expressed interest to be involved or add these activities

in the scope of work for the TF and that the Research TF has included activities related to the shorter regimen in their plans. After due discussion and deliberations the CG agreed on several action points listed below.

The proposal on the "Human Rights and the Law" Task Force was discussed and most of the CG members expressed interest in this proposal. At the same time, several questions raised by the CG members would need to be answered and group felt that more details on the plans, deliverables and activities of the proposed TF would be needed before taking a decision. The CG agreed therefore to invite the lead person behind this proposal for a presentation and Q&A session during next CG meeting or conference call.

In a session with participation of Heather Alexander (GLI chair), the CG has discussed creation of the new TF linking two working groups – the GDI-GLI Task Force. Several discussions have already taken place in the group and between chairs of the WGs, some GDI CG members have volunteered to be part of the TF. The discussion during the meeting has confirmed strong interest from the GDI towards creation of the Task Force and GLI chair has suggested a couple of areas of work: translation of the new diagnostic and treatment policies into a linked implementation guidance using an example of SL-LPA and the shorter MDR-TB regimen; improvement of uptake of new DST technologies (for example Xpert MTB/RIF) into patient care cascades by identifying and bridging the gaps in integration of rapid diagnosis into clinical decision pathways. During discussion a potential benefit of including the GDF into this TF was highlighted and its possible assistance with forecasting of needs of both diagnostic tools and medicines for the relevant regimens was considered important for the work of this TF. The GDF representative supported this linkage and expressed clear interest on behalf of GDF to become part of this TF.

Action points:

- DR-TB STAT TF to document the successful and less successful models of new TB drugs' introduction and present it to the CG with eventual plan of making this summary available to countries and their partners.
- DR-TB Research TF to review and update the short MDR-TB regimen protocol so it could be used both for establishing use of these regimen within operational research and programmatic implementation environments.
- DR-TB STAT and DR-TB Research TFs to discuss and consider best ways to include activities supporting shorter MDR-TB regimen implementation in the scope of work of one or both TFs, also linking with the partners like MSF, UNION, KNCV for potential synergies, expertise and funding.
- Secretariat to invite the proponent of the "Human Rights and the Law" Task Force for a presentation and Q&A session during one of the upcoming CG conference calls or in-person meetings.
- To create a new GDI-GLI TF, also including GDF representative. First conference call to be scheduled in August 2016 and an in-person meeting in Liverpool in October.

Session 5: Review of the GDI Framework document.

The time during this session was dedicated to discussing the draft of the GDI Costed Framework document prepared by a consultant. It has therefore touched upon the roles of the GDI and focus areas for its current and future Task Forces, advocacy and way to address the advocacy needs in collaboration with the Stop TB Partnership team and the tentative budget as presented in the draft document.

The summary of the document as presented in recent conference call by the CG vice-chair was reviewed and the group decided:

- To prioritize several strategic areas of work and include as priority the introduction of new TB drugs and new regimens, integration of diagnostics and treatment activities, advice, mapping and guiding the agenda for MDR-TB related research. Other areas of work can be included based on the need and available expertise and resources.
- To continue forming or accepting proposals for specific Task Forces that map well into the strategic areas of work.
- To formulate and present to the Stop TB Partnership the high level advocacy needs as identified by the CG.
- To revise the estimates in the budget presented in the framework document based on feedback from current and previously active Task Forces and revise regional presence budget line, which was considered unnecessary by the CG.
- To explicitly include the expected inputs and participation of the civil society in the document with support of the CS constituency representative in the CG.
- For the Secretariat to proceed with development of the next version of the document based on this feedback and present a new, pre—final version to the CG for endorsement.

Summary of action points

General:

- To formulate and present to the Stop TB Partnership the high level advocacy needs as identified by the CG and solicit possible suggestions for a high level advocacy on importance of MDR-TB management in order to nurture and boost political commitment in affected countries.
- For rGLC chairs, to discuss with respective committees and regional secretariats their suggestions on possible avenues of interactions and support from the GDI to the rGLCs.
- To organise a dedicated meeting (potentially a conference call or a meeting in Liverpool during UNION conference) of GDI with the rGLCs and their secretariats and the GF to discuss mechanism for expanded collaboration, platform for regular knowledge and experience sharing and clear assignment of roles and responsibilities.
- To develop a brief document (2-3 pager) following the meeting above that would clarify the roles and relationships of GDI and the rGLCs.

Task Forces:

- DR-TB STAT TF to document the successful and less successful models of new TB drugs' introduction and present it to the CG with eventual plan of making this summary available to countries and their partners.
- DR-TB Research TF to review and update the short MDR-TB regimen protocol so it could be used both for establishing use of the regimen within operational research and programmatic implementation environments.
- DR-TB STAT and DR-TB Research TFs to discuss and consider best ways to include activities supporting shorter MDR-TB regimen implementation in the scope of work of one or both TFs, also linking with the partners like MSF, UNION, KNCV for potential synergies, expertise and funding.
- Secretariat to invite the proponent of the "Human Rights and the Law" Task Force for a presentation and Q&A session during one of the upcoming CG conference calls or in-person meetings.
- To create a new GDI-GLI TF, also including GDF representative. First conference call to be scheduled in August 2016 and an in-person meeting in Liverpool in October.

GDI Costed Framework document:

- Prioritize several strategic areas of work and include as priority the introduction of new TB drugs and new regimens, integration of diagnostics and treatment activities, advice, mapping and guide the agenda for MDR-TB related research. Other areas of work can be included based on the need and available expertise and resources.
- To continue forming or accepting proposals for specific Task Forces that map well into the strategic areas of work.
- To revise the estimates in the budget presented in the framework document based on feedback from current and previously active Task Forces and revise regional presence budget line, which was considered unnecessary by the CG.
- To explicitly include the expected inputs and participation of the civil society in the document with support of the CS constituency representative in the CG.
- For the Secretariat to proceed with development of the next version of the document based on this feedback and present a new, pre—final version to the CG for endorsement.

Annex 1. Agenda

AGENDA

5th Meeting of the Core Group of the Global Drug−resistant TB Initiative
8 July 2016, Geneva, Switzerland

Chair: Charles Daley
Secretariat: Fuad Mirzayev

09:00	**Meeting objectives and declaration of interests**	**Secretariat**
Session 1: Action points from previous meetings		
09:30	Follow up on action points from 4th GDI CG meeting and monthly teleconferences	**Secretariat**
Session 2: New WHO policy guidance		
09:45	New WHO guidelines on MDR-TB management New WHO guidance on TB diagnostics	**Dennis Falzon** **Alexei Korobitsyn**
10:30	**Coffee break**	
Session 3: MDR-TB scale up in regions: updates from regional GLCs, how GDI and rGLCs can interact better		
11:00	AFRO; AMRO; EMRO; EURO; SEARO; WPRO	**rGLC chairpersons**
12:30	Discussion on how GDI can help in capacity building and support the rGLC mechanism.	
13.00	**Lunch**	
Session 4: GDI Task Forces		
14:00	DR-TB STAT Task Force progress update New Task Forces: GDI-GLI Task Force, new Task Force proposals	**Jennifer Furin** **Secretariat**
Session 5: Review of the GDI framework document		
15:00	Facilitated discussion • roles of the GDI • potential activities and task forces that map into the roles identified • advocacy areas for GDI to address • budget to be presented in the document	**Chair**
16:00	**Coffee break**	
16:30	Next steps in document development	**Chair**
17:30	**Wrap up and next steps**	

Annex 2. List of Participants

GDI Core Group

Sarabjit Chadha
The Union, South East Asia Officer
C-6, Institutional Area
New Delhi 110030
INDIA
Email: drsschadha@gmail.com

Daniela Maria Cirillo
Head, Supranational Reference Laboratory
Fondazione Centre San Raffaele
Via Olgettina, n. 60
20132 - Milano
ITALY
Email: cirillo.daniela@hsr.it

Charles Daley
GDI Chair
Chief, Division of Mycobacterial and Respiratory Infections
National Jewish Health
1400 Jackson Street
Denver, CO 80206
UNITED STATES OF AMERICA
Email: DaleyC@njhealth.org

Gunta Dravniece
KNCV
Altingstraat 205
2593 SW Den Haag
NETHERLANDS
Email: gunta.dravniece@kncvtbc.org

Essam Elmoghazy
Chair, EMR rGLC
National TB Programme
Heliopolis, Cairo
EGYPT
Email: elmoghazy55@gmail.com

Sirinapha Wungmanee Jittimanee
Bureau of Tuberculosis
Department of Disease Control
Ministry of Public Health
116 Sudprasert Rd., Bangkholaem,
Bangkok 10120
THAILAND
Email: sxj2014@yahoo.com

Saira Khowaja
Director, Program Development
Interactive Research & Development
Suite 508, Ibrahim Trade Tower
Main Sharrah−e−Faisal
75350 - Karachi
PAKISTAN
Email: saira.khowaja@irdresearch.org

Rafael Laniado Laborin
Chair, AMR rGLC
R Hospital General de Tijuana
Instituto Estatal de Salud de Baja California
Tijuana
MEXICO
Email: rlaniado@uabc.edu.mx

Andrey Maryandyshev
Chair, GLC\Europe
Head of the Phthisiopulmonology Department
Northern State Medical University
Troitsky 51
163061 - Arkhangelsk
THE RUSSIAN FEDERATION
Email: maryandyshev@mail.ru

Subrat Mohanty
Project Coordinator
The UNION, India
New Delhi 110016
INDIA
Email: SMohanty@theunion.org

Kwonjune Justin Seung
Partners in Health
Boston
UNITED STATES OF AMERICA
Email: kjseung@gmail.com

Carrie Tudor
Co−Chair of IC sub−group,
Durban
SOUTH AFRICA
Email: tudor@icn.ch

Jacques van den Broek
Chair, WPR rGLC
Interim Technical coordinator of the
KNCV/Challenge TB office
MALAWI
Email: jacvdbroek@planet.nl

Observers

Jennifer Furin
DR-TB STAT task force leader
Cleveland,
UNITED STATES OF AMERICA
Email: jenniferfurin@gmail.com

Mohammed Yassin
Senior Advisor
The Global Fund
Chemin de Blandonnet 8
1214 Vernier – Geneva
SWITZERLAND
Email: Mohammed.yassin@theglobalfund.org

Brenda Waning
GDF manager
Geneva
SWITZERLAND
Email: brendaw@stoptb.org

Kaspars Lunte
GDF
Geneva
SWITZERLAND
Email: luntek@stoptb.org

WHO HQ

Alexei Korobitsyn, GTB
Dennis Falzon, GTB
Medea Gegia, GTB
Malgosia Grzemska, GTB
Ernesto Jaramillo, GTB
Fuad Mirzayev, GTB

Annex 3. Summary of Declaration of Interests

All core group members who participated in the meeting completed Declaration of Interests (DoI) form. No significant conflicts of interest were declared. Three CG members made the following disclosures that were considered insignificant in relation to the subjects discussed during the meeting: Charles Daley have served in an advisor capacity in scientific committees convened by Otsuka and Novartis; Carrie Tudor is employed by the International Council of Nurses (ICN) – the organisation that received a grant from the Eli Lilly Foundation in 2013; Gunta Dravniece was employed in the pharmaceutical division of Otsuka in 2013-15.

Annex 4. GDI Core Group (as of July 2016)

Name	Surname	Affiliation	Constituency	Status
Hind	Satti	Partners in Health, USA	AFRO rGLC chair	member
Rafael Laniado	Laborin		AMRO rGLC chair	member
Subrat	Mohanty	The UNION, India	Civil society, patients and affected communities	member
Amy	Bloom	USAID	Donor/ funding agencies	member
Essam	Elmoghazy	National TB Programme, Egypt	EMRO rGLC chair	member
Andrey	Maryandyshev	Northern State Medical University, Russian Federation	EURO rGLC chair	member
Charles	Daley	National Jewish Health, USA	GDI chair	member
Agnes	Gebhard	KNCV, Netherlands	GDI vice-chair	member
Sirinapha Wungmanee	Jitimanee	National TB Programme, Thailand	National TB programmes of high DR–TB burden countries	member
Kuldeep Singh	Sachdeva	National TB Programme, India	National TB programmes of high DR–TB burden countries	member
Carrie	Tudor	International Council of Nurses , South Africa	National/international/ scientific/professional medical associations and nursing associations	member
Saira	Khowaja	IRD, Pakistan	Private for profit sector	member
Sarabjit	Chadha	The UNION, India	SEARO rGLC chair	member
Chen-Yuan	Chiang	The UNION, France	Technical agencies and implementation partners assisting NTPs of high burden DR–TB countries	member
Daniela	Cirillo	Fondazione Centro San Raffaele, Italy	Technical agencies and implementation partners assisting NTPs of high burden DR–TB countries	member
Kwonjune Justin	Seung	Partners in Health, USA	Technical agencies and implementation partners assisting NTPs of high burden DR–TB countries	member
Jacques	van den Broek	KNCV, Netherlands	WPRO rGLC chair	member
Mohammed	Yassin	Global Fund	Donor/ funding agencies	observer
Heather	Alexander	CDC, USA	GLI chair	observer
Jennifer	Furin	chair of DR-TB STAT Task Force	Non–governmental sector partners	observer
Andre	Zagorski	GDF, Switzerland		observer
Fuad	Mirzayev	WHO, Switzerland	WHO secretariat	secretariat