



# **THIRD MEETING OF THE CORE GROUP OF THE GLOBAL DRUG- RESISTANT TB INITIATIVE**

**1 MAY, 2015  
GENEVA, SWITZERLAND**

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## List of Participants

### GDI Core Group

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The Union  
Spain
2. **Amy Bloom**  
USAID  
USA
3. **Chen-Yuan Chiang**  
The Union  
France
4. **Daniela Maria Cirillo**  
HSR San Raffaele Scientific Institute (SRL Milan)  
Italy
5. **Charles L. Daley, GDI Chair**  
National Jewish Health  
USA
6. **Essam Elmoghazy, Chair, EMR rGLC**  
Cairo Association against Smoking, Tuberculosis  
and Lung diseases  
Egypt
7. **Agnes Gebhard, GDI Vice-Chair**  
KNCV  
The Netherlands
8. **Saira Khowaja**  
IRD  
Pakistan
9. **Norbert Ndjeka, representing AFR rGLC.NTP (MDR TB Focal Point)**  
South Africa
9. **Lee Reichman, Chair, WPR rGLC**  
New Jersey Medical School, Rutgers  
USA
10. **Kuldeep Singh Sachdeva**  
Ministry of Health and Family Welfare  
India
11. **Rohit Sarin, Chair, SEAR rGLC**  
National Institute of TB and Respiratory Diseases  
(SRL National Center of Excellence)  
India
12. **Carrie Tudor, Chair, IC sub-group**  
International Council of Nurses  
South Africa

### Observer

13. **Joel Keravec**  
GDF, Stop TB Partnership  
Switzerland
14. **Thomas M Shinnick, GLI Chair**  
US Centers for Disease Control and Prevention  
USA

**15. Mohammed Yassin**

The Global Fund  
Switzerland

**WHO**

16. **Karin Weyer**, HQ/GTB-LDR, Coordinator
17. **Dennis Falzon**, HQ/GTB-LDR
18. **Medea Gegia**, HQ/GTB-LDR
19. **Ernesto Jaramillo**, HQ/GTB-LDR
20. **Fuad Mirzayev**, HQ/GTB-LDR
21. **Linh Nhat Nguyen**, HQ/GTB-LDR
22. **Fraser Wares**, HQ/GTB-LDR
23. **Diana Weil**, HQ/GTB-PSI, **Coordinator**
24. **Christian Lienhardt**, HQ/GTB-PSI
25. **Martin van den Boom**, EURO

Present for Summary Session 3

26. **Mukadi YaDiul**, USAID, USA
27. **Jennifer Furin**, Harvard Medical School, USA
28. **Lucica Ditiu**, Executive Secretary, TBP, Geneva, Switzerland
29. **Grania Brigden**, MSF, Geneva, Switzerland
30. **Anna Scardigli**, GF, Geneva, Switzerland

## **Background**

This was the third meeting of the Global Drug Initiative's (GDI) Core Group (CG) coordinated by the GDI secretariat housed in the Laboratories, Diagnostics and Drug resistance (LDR) unit of the Global TB Programme GTB/WHO.

## **Welcome address**

Dr Charles Daley, Chair of the CG welcomed the participants and informed them about the purpose of the meeting, along with an overview of the agenda. He reminded the participants that one of the tasks for the meeting will be follow up the discussions held on GDI/GLI forum, 27 – 30 April 2015.

## **Meeting objectives**

The meeting objectives were:

- To follow up on recommendations from the GDI/GLI forum, including the issue of the “call to action on the introduction of new anti-TB drugs”;
- To follow up on recommendations and action points agreed upon during 2<sup>nd</sup> GDI CG meeting and subsequent monthly teleconferences;
- To provide an update on the progress of the GDI Task Forces, and the Infection Control (IC) sub-group;
- To review the strategic priorities of GDI and plan subsequent activities for the next year; and
- To discuss the GDI "costed framework" and the work plan.

## Summary of discussions and recommendations from the GDI/GLI forum and implications on Joint GDI and GDI CG activities in 2015-2016

This discussion started with a follow up of the session 3: Introduction and access to new anti-TB drugs from the Joint Partners Forum, where a wide range of stakeholders (USAID; Otsuka; WHO/GTB; UNITAID; GF; Stop TB/GDF) provided updates on the current situation and future plans regarding the introduction of new anti TB drugs. It was stressed that although bedaquiline (Bdq) and delamanid (Dlm), two new anti-TB drugs, are now licensed in a few countries, access and uptake at country levels has been slow. This slow progress prompted MSF and 88 other civil society organizations to publish a public "Call to action" open letter on 10 March 2015 with a number of requests to industry and other stakeholders regarding access to the 2 new drugs.

The presentation on behalf of 88 co-signatories was made by Grania Brigden at the Joint Partners Forum. She reminded the audience that approval of bedaquiline was granted in December



2012 and for delamanid in April 2014. WHO guidance on the programmatic use of Bdq was issued in June 2013 and for Dlm in November 2014. Recently USAID has announced a donation programme for Bdq in April 2015. Despite all these positive actions, up-to-date only 600 patients are on Bdq and less than 50 on Dlm outside of clinical trials. Hence, MSF and other organisations have proposed the establishment of an "action team" to advocate and monitor increased access to the new and repurposed DR-TB drugs in 50 top high-burden countries through greater collaboration by the major actors. During her talk, Dr Brigden posed a number of queries, e.g. how can the key actors work together to ensure all patients requiring new drugs have access to the new drugs; what other barriers need to be addressed; and what actions need to be taken by the GDI CG to achieve these goals within the next 6 months and 12 months? The discussions were also a continuation of the discussions during the Joint GDI/GLI Partners Forum on how to avoid overlap of platforms and duplication of actions as well as structures.

Following discussions between the GDI CG members and interested participants from the Joint GDI/GLI Partners Forum, there was general consensus that no-one wanted any “new” structures outside of considering a new Task Force.

The importance of understanding of the respective country level situation was stressed. A top down and bottom up approach is needed to tackle this. The capacity of both the members of the rGLCs and the existing PMDT consultants needs to be built to take on board the issues raised here.

Dr Charles Daley, GDI chair, suggested that the GDI platform and with its Task Force structure, seemed to be the most appropriate "house" for this activity, and that the energy behind the "call for action" would bring a real sense of focus and purpose of intent with it.

The CG agreed that the creation of a GDI Task Force to address this issue was the best solution. MSF will now discuss this suggestion with the other partner organizations involved in the “call to action” campaign. The GDI secretariat verbally provided the necessary information on the template and structure of concept note for GDI taskforces. If the suggestion of creating a GDI Task Force to address this issue is agreed by MSF and the partner organizations, MSF will draft a concept note for such a Task Force and submit it to the GDI Chair and Secretariat as soon as possible.

The CG members then subsequently discussed a number of other issues raised during the Joint GDI/GLI Partners Forum. These included: how best to introduce the whole suite of molecular based DST in countries; need to train the attending clinicians on how to "use" DST results, especially molecular based ones; transportation of samples to DST sites and timely transmission of results to the attending doctors in order for them to take the appropriate treatment action; how to expand the GLI network and link them to the rGLCs; and need for review and updating of WHO guidance on SL DST by LPA and shorter regimens. A list of tentative issues to be discussed with the GLI CG, was also developed for future joint GDI/GLI activities.



## Joint GDI/GLI Core Group Meeting

A combined session of the Global Laboratory Initiative (GLI) CG and the GDI CG was held to discuss the issue of growing gaps between the number of MDR-TB cases detected and the numbers started on treatment. GDI and GLI chairs also reviewed the recommendations from the previous joint meeting, as well as relevant issues raised during the Joint GDI/GLI partners forum.

One important issue raised during the forum was the need to scale up molecular testing for 2nd line anti-TB drugs. Dr Thomas Shinnick, GLI Chair, informed the meeting that the 2<sup>nd</sup> line LPA DST will be re-evaluated by WHO in October, 2015. Hence by November, 2015 when WHO starts the updating of the MDR-TB treatment guideline, the final recommendations from the Expert Group Meeting on 2nd line anti-TB testing will be available.

Some CG members suggested to the GLI CG the need to extend the regional GLI network as currently only three rGLIs are established and functional. GDI and GLI CG members had extensive discussions on field experiences and the possible reasons for the growing gap between diagnosis and treatment. A number of suggestions were proposed, including the development of a tool for identifying "gaps" and the reasons for this. This could be a topic for a joint GDI/GLI Task Force.



As new drugs are rolled out, DST for these drugs also needs to be rolled out. Such DSTs are currently under development. It will be important that the GLI is represented on any new Task Force established to increase access to new drugs.

Closer working between the GLI and the GDI Infection Control (IC) sub-group is needed in the area of laboratory biosafety and infection control more generally. It is important that laboratory concerns are adequately represented within the IC sub-group.

A joint action plan based on these ideas will be crystallized further in the coming weeks, including possible Task Forces to be established.

### **Updates on GDI secretariat**

Medea Gegia, on behalf of GDI secretariat, presented the actions taken by the GDI Secretariat on the recommendations made during the 2nd CG meeting. The activities undertaken against the main recommendations are as listed below:

1. Organize monthly GDI CG calls on the first Friday of each month
  - Monthly conference calls using WebEx have been regularly held since the 2<sup>nd</sup> GDI CG meeting, with a total of 5 CG conference calls held to date.
2. Convene a small group meeting of CG members to develop a draft of the GDI "costed framework" document in early 2015
  - GDI secretariat organized a small GDI CG meeting in Geneva, at GTB/WHO, from 27 to 28 January 2015. The small group developed a draft of the "costed framework" document which needs to be finalized in the coming months and shared with all CG members for endorsement.
3. To explore with the TBP Secretariat, the administrative processes that need to be completed for the IC subgroup to move under the GDI umbrella and to provide the IC sub-group with a seat on the GDI CG;
  - The administrative process required for supporting the move of the IC sub-group to be under the GDI umbrella has been completed. The IC sub-group has a seat on the GDI CG in the person of the IC sub-group Chair.

4. Publish the 2nd GDI newsletter in close coordination with the three taskforces and partners
  - A draft of the 2nd issue has been prepared by the GDI secretariat, and will be shared to Core Group members in June 2015 for finalisation and subsequent publication. Hard copies could be distributed during the 4<sup>th</sup> CG meeting and the Union conference in December 2015. Electronic version will be made available via the GDI listserv and TBP website.
  
5. Maintain GDI webpages on the Stop TB Partnership (TBP) website. Immediate action is to update it with a summary of the GDI CG meeting
  - GDI webpages are being regularly maintained. Recently the progress of the 3 Task Forces was highlighted and updated.
  
6. Plan for the next GDI CG meeting on 1 May 2015 in Geneva after the Joint Partners Forum. The meeting will also be an opportunity for Task Forces (TF) to present and discuss their action plan along with progress on the plan to the CG members
  - 3<sup>rd</sup> GDI CG meeting being held on 1 May in Geneva as planned. TF leaders had an opportunity to present actions taken to date and the next steps during the Joint GDI/GLI Partners Forum.
  - Proposed to hold the 4<sup>th</sup> GDI CG meeting in Cape Town, South Africa on 1 December 2015 prior to The Union World Lung Health Conference.
  
7. The GDI and GLI Chairs, and respective Secretariats to coordinate the finalisation of a set of proposed joint GDI/GLI activities proposed at the 1<sup>st</sup> GDI/GLI CG meeting in Barcelona
  - GDI /GLI secretariat with the support of GDI and GLI chairs has made some progress towards the activities planned jointly. However further development of a joint action plan needs to be taken after the 2<sup>nd</sup> joint meeting on 1 May 2015.

## Other actions taken by the secretariat

- ✓ Maintained the GDI listserv, which now has more than 300 subscribers. This is an open listserv and any interested person can subscribe to it.
- ✓ Oversaw administrative and contractual process for distribution of funding to the 3 GDI Task Forces on Advocacy, Patient Centred Care (PCC) and Research.
- ✓ Participated and coordinated with the rGLCs for the external evaluation of the 'GLC MoU' between the GF and WHO. Organised the briefing meeting on the evaluation of the GLC related MoU with the GF and potential future support for PMDT on 10 March 2015.
- ✓ Drafted a proposal for FY 2015 USAID funding of the GDI Working Group.
- ✓ Maintained coordination with the GLI Secretariat and GDF on relevant issues.
- ✓ Oversaw the finalisation of the WHO's training manuals of the "Management of DR-TB training for staff working at DR-TB treatment centres".
- ✓ Oversaw the process to fill the vacant position on the GDI Core Group, including placement of the open "call for applications", creation of a shortlisting group and support to its work.



## Updates from the meeting on developing of the “GDI costed framework” and the next steps

This meeting was held following a request made in the 2<sup>nd</sup> meeting of the GDI CG on 27 October 2014. The CG proposed that the GDI secretariat convene a small group meeting of CG members that would develop the first draft of the “costed GDI framework” document, which later will be circulated to the full CG for review and comment.



The GDI secretariat organized a two-day small group meeting in Geneva, Switzerland on 27-28 January 2015. The CG group members discussed broadly the existing challenges and agreed on the following priority areas for GDI to work on: Advocacy; Linkage of diagnostic and treatment of MDR-TB patients; Capacity building; and Technical support. The participants worked on the two broad areas of “Advocacy and linkages” and “TA support and capacity building” resulted in draft sections of the “costed framework document” being developed. However the documents is not yet completely drafted or finalized.

The CG agreed that any “costed framework document” needs to take the big and broad vision on diagnosis, treatment and all other required elements for the care of MDR-TB patients, what resources will be required to achieve this, and how all partners can be brought into the envisaged required activities.

The CG proposed that the GDI secretariat hires a consultant to develop a final complete draft of said document as soon as possible. This would then be shared with all CG members for their inputs and endorsement.

## Updates on Task forces

Presentations by the GDI taskforces on Advocacy, Patient Centered Care (PCC) and Research taskforces, as well as the GDI Infection Control sub-group, were made by the taskforce leaders during the Joint Partners Forum on 30 April 2015. The next steps were discussed during the CG meeting on May 1 2015.

The draft generic protocol for shorter regimens for the treatment of MDR-TB patients developed by Research Task Force, has been through two rounds of reviews including by a small group of CG members. It was clarified that the protocol was intended as a



generic guidance note which needs to be adapted to the respective local setting prior to implementation, and not as a handbook or set of recommendations on shorter regimens.

The CG agreed that the final version of the generic protocol, incorporating all the comments and feedback received so far, is to be circulated to all CG members for their final inputs and endorsement within the next 2 weeks. Subsequently the final product will be posted on the GDI webpage of the TBP website.

The CG also agreed that once a Task Force has completed its stated activities, then it will be closed. Any maintenance activities or linkages with other groups, will be performed accordingly and as per available resources. Hence the Task Forces for Advocacy and Patient Centred Care are now closed. The Research TF will continue its work until August 2015.

## Update on funding for the GDI

The situation regarding funding for the GDI was presented by Dr Fraser Wares, GDI secretariat. The granting and distribution of funds from different donor agencies were summarized. It was highlighted that currently the available funds are predominantly earmarked to support GDI CG and annual GDI meetings, and the GDI Secretariat, with minimal funds available to support other GDI activities.

The previous Memorandum of Understanding (MoU) between the Global Fund (GF) and WHO on GLC-related activities ended on 31 March 2015. The proposed new amended MoU, for the period April 2015 to December 2016, is currently under legal review. In the amended MoU, contributions to the GLC Initiative will continue to be paid out of the country GF grants. However there will be differentiation in the contribution and support to the mechanism, based on the estimated MDR-TB caseload of the respective country.

A new element of the new amended MoU will be performance based disbursement of the GLC related annual payment to ensure the provision of quality assured services. Hence the annual GLC contribution would be paid in two tranches: \$15,000 to be paid up front to support the rGLC mechanism/ structures; and the balance, which is intended to support the monitoring and/or TA missions (i.e. \$10,000 or \$35,000), will be paid after a peer reviewed mission report is received by GF.

The revised USAID Financial Year 2014 grant also has a component supporting MDR TB management scale up for the countries with GF grants with MDR-TB component. The following objectives of the grant were discussed broadly:

- Support adoption and operationalization of the new WHO policies, guidelines on MDR-TB diagnosis and treatment, in selected priority countries.
- Support selected priority countries in their efforts to align increase in MDR-TB case finding with appropriate treatment and management of patients using current and new approaches, including new TB drugs.
- Monitor and follow up the progress of selected countries in PMDT scale-up, review, analyze TA and monitoring reports and document barriers to implementation of related activities supported through this grant and other partners.
- Implemented via two Units of WHO's GTB Programme, and many collaborating organizations, including FIND and WHO's Supranational Reference Laboratory Network



## Review of vision and strategic priorities of GDI

This session was led by Dr. A. Gebhard and Dr. Ch. Daley. The following 6 strategic priorities were identified during the previous CG meeting:

1. Facilitate integration and coordination of efforts to align diagnostic services for patients with access to high-quality care;
2. Develop targeted advocacy strategies and resource mobilization for DR-TB management scale-up;
3. Build global consensus on management of DR-TB for patient-centred care delivery ("care for cure")
4. Promote strategies to facilitate patient access to high-quality DR-TB care, through in-country capacity building approach targeting public and private sector;
5. Facilitate effective knowledge sharing among partners and harmonise coordination with existing technical assistance mechanisms to ensure quality support to PMDT;
6. Support prioritization of research to generate evidence for PMDT scale-up.



It was agreed that the strategic priorities of GDI should be a living document, being re-prioritized based on lessons learnt, as well as taking into consideration new issues as they arise. Although already diffusely covered by the existing priorities, the area of work proposed during the Joint GDI/GLI CG meeting, namely "facilitate integration and co-ordination of efforts to align diagnostic services for patients with access to high quality care" needs to be clearly reflected in the priorities.

The CG members agreed that two new items, namely strengthening infection control and accelerating access to new anti-TB drugs, should be added to the current list of strategic priorities. The CG Chair and GDI Secretariat will revise the current list of strategic priorities and share the draft with the CG for their inputs and comments.



## Recommendations and follow-up action points

- GDI secretariat to provide the template of the Task Force concept note to MSF on behalf of the “call to action” campaign group, and follow up with MSF the next steps for establishing a new GDI TF as discussed and proposed.
- GDI secretariat to send out to the CG members the shortlist and CVs of the shortlisted candidates for review and voting on, and follow up on the voting process for the selection of the new CG members. Once available, subsequently share the voting results with the CG members.
- As requested by the GDI CG, the GDI secretariat to hire a consultant to develop the final draft of the GDI "costed Framework" document. Subsequently GDI Secretariat to share the draft document with the CG members for review and comments prior to its finalization.
- GDI and GLI Chairs, and the respective Secretariats, to coordinate and follow up the set of proposed joint GDI/GLI activities.
- CG Chair and GDI secretariat to draft a revised list of strategic priorities, which will be subsequently shared with the CG members for their their inputs and comments prior to its endorsement.
- GDI secretariat to finalize the 2nd issue of the GDI newsletter, share it with the CG members for endorsement prior to its posting on the GDI webpage.
- GDI secretariat to start the preparations for the 4th CG meeting on 1 December 2015 prior to The Union conference in Cape town, South Africa. Representative of the TB Alliance to be invited to the meeting as an "Observer".
- GDI secretariat to request the GDF to update the CG during the regular TCs on the availability of Bdq and the progress of the EWS system roll out.
- Chair or Vice Chair of the CG to contact the lead person in LDR Unit to request the participation of 1 or 2 persons from the CG in the Guideline Development Group for the development of the WHO consolidated TB treatment guidelines.
- GDI secretariat to post the updates and documents from the GDI Task Forces and IC subgroup on the GDI webpages, and regularly update the GDI webpages.
- GDI secretariat with the GDI Chair to plan the next GDI CG TC in the first half of June 2015.

- GDI secretariat to poll the CG members on any "missing groups" who are currently not represented in the CG.
- IC sub-group to send its annual workplan and budgets to the GDI Chair and GDI Secretariat.

## Annex 1

**JOINT PARTNERS FORUM  
FOR STRENGTHENING AND ALIGNING TB DIAGNOSIS AND TREATMENT**

GLI / GDI Partners Forum  
WHO Executive Board Room, Geneva, 2015

<b>Friday, 1 May, 2015</b>		
<b><u>GDI CORE GROUP MEETING</u></b>		<b>Chairs: Charles Daley &amp; Fraser Wares</b>
09.00 – 09.45	Summary of discussions and recommendations from the GDI/GLI forum and implications on GDI and GDI CG activities in 2015–2016 1. Introduction and access to new drugs: call to action on the introduction of bedaquiline and delamanid Discussion	Charles Daley & Agnes Gebhard / Grania Brigden
09.45 – 10.30	Summary of discussions and recommendations from the GDI/GLI forum and implications on GDI and GDI CG activities in 2015–2016 2. Other sessions of meeting Discussion	Charles Daley & Agnes Gebhard
<b>10.30 – 11.00 COFFEE BREAK</b>		
<b>Joint meeting with GLI CG</b>		<b>Chairs: Charles Daley &amp; Tom Shinnick</b>
11.00 – 13.00	Summary of discussions and recommendations from the GDI/GLI forum and implications on Joint GDI/GLI activities in 2015–2016	Charles Daley & Tom Shinnick
<b>13.00 – 14.00 LUNCH</b>		
14.00 – 14.20	Report from the GDI Secretariat	Medea Gegia
14.20 – 14.40	Brief summary of output from drafting meeting of the "GDI costed framework"	Charles Daley & Agnes Gebhard
14.40 – 15.30	Updates on Task Forces, including presentation of generic protocol for shorter regimens	Agnes Gebhard & CY Chiang, Carrie Tudor, Jonathan Smith
<b>15.30 – 16.00 COFFEE BREAK</b>		
16.00 – 16.15	Funding situation	Fraser Wares
16.15 – 16.45	Review of vision and strategic priorities of GDI	Charles Daley
16.45	Priority activities for next year for the GDI CG	Charles Daley & all CG members
17.15	Summary and next steps	Charles Daley & Agnes Gebhard
17.30	End of Day 5	

