

## Leadership Team Meeting

7 April 2021

### Participants

#### Leadership team members and guests

- Amar Timalina, President, International Association for Integration, Dignity and Economic Advancement (IDEA) Nepal
- Arielle Cavaliero, Global Franchise Lead, Leprosy, Novartis
- Benedict Quao, Program Manager, National Leprosy Elimination Program of Ghana
- Bill Simmons (Chair), President & CEO, American Leprosy Missions
- Erwin Cooreman, Team Leader, WHO Global Leprosy Programme
- Gangadhar Sunkara, Senior Global Program Clinical Head, Novartis
- Geoff Warne, CEO, International Federation of Anti-Leprosy Associations (ILEP)
- Linda Hummel, Chair of Executive Group, Leprosy Research Initiative (LRI)
- Maarten van Cleeff, Former Director of Challenge TB project, KNCV
- Petra Kukkaro, Precision Medicine Associate Director, Global Drug Development, Novartis
- Roch Christian Johnson, President, International Leprosy Association
- Takahiro Nanri, Executive Director, Sasakawa Health Foundation
- Wim van Brakel, Chair, ILEP Technical Commission (ITC)

#### Secretariat

- Andie Tucker, Project Manager, Global Partnership for Zero Leprosy
- Bill Gallo, Secretariat Director, Global Partnership for Zero Leprosy
- Caroline Cassard, Communications Specialist, Global Partnership for Zero Leprosy
- Mondie Tharp, Project Manager, Global Partnership for Zero Leprosy

#### Invited but unable to attend

- Alice Cruz, UN Special Rapporteur
- Mathias Duck, Chair of ILEP Panel of Persons Affected by Leprosy
- Mauricio Lisboa Nobre, Consultant to Brazilian Leprosy Program
- Rao Pemmaraju, Technical Officer, WHO Global Leprosy Programme
- Rekha Shukla, Joint Secretary, Ministry of Health and Family Welfare, India

## I. Leprosy Diagnostic Presentation and Q&A: Petra Kukkaro

- **Petra Kukkaro:** I co-chair the Diagnostic Working Group with Sundeep. I work at Novartis as a global biomarker diagnostic associate director. I support diagnostic projects in various disease areas. *See presentation.*
- **Maarten van Cleeff:** The Foundation for Innovative New Diagnostics (FIND) would be an excellent partner.
  - **Petra Kukkaro:** We have not been in contact with FIND. Within our team and the WHO NTD Diagnostic Technical Advisory Group (DTAG), we have avenues to reach out to them.
- **Wim van Brakel:** The Task Force for Criteria for the Elimination of Leprosy (TFCEL) prefers “interruption of transmission” instead of “elimination of transmission.” It seems that this TPP model could be applied to other research priorities or could be taken a step further with our upcoming workshops.
- **Geoff Warne:** You used the words, “partner reach and negotiation.” If WHO DTAG validates this, that is an asset for resource mobilization. What does this process look like for Novartis?
  - **Petra Kukkaro:** WHO approval is helpful for resource mobilization. Gates Foundation wants to be confident that it will lead to products that will reach the community. Who would be the right person? What are the roles and responsibilities of partnership? The working group doesn’t have the mandate to work on this. I hope we can have this conversation with the resource mobilization group. We should not stop with our TOR.
- **Geoff Warne:** At Novartis, when would the Business Development and Licensing (BD&L) team begin? When landscaping potential funders or once the TPP has advanced to a certain point?
  - **Petra Kukkaro:** We have the TPP developed, the landscaping, and potential vendors identified. That work has been done with commercial support. At the same time we secure the funding for diagnostic development. Once both of those pieces are in place, BD&L can begin. They cannot negotiate if they don’t have secured funding.
- **Linda Hummel:** What can we do to support you to make this a success?

- **Petra Kukkaro:** If there are individuals in this group that could fill gaps and support any discussions with vendors, it would be easier to put the roles and responsibilities in place. We need a mapping process to create a framework and move forward efficiently.
- **Bill Simmons:** Could you describe 1) How do you see the use case? What's the target benefit? 2) What is the timeline for David Blok's engagement, to demonstrate if there would be an impact?
  - **Petra Kukkaro:** David Blok completed his work and those assumptions have been captured in the TPP. The assumption was we need to have a diagnostic that will benefit in the long term. The time frames are long because it will take a long time to see an impact. It's all incremental alongside other aspects of leprosy work. It's grounded in David Blok's modeling, which shows it will create impact. It's not a magic bullet, but it will move the needle another inch.
- **Bill Simmons:** If subclinical leprosy is diagnosed, does the diagnostic introduce full regimen MDT? What is the Diagnostic Working Group's thinking on treatment change?
  - **Petra Kukkaro:** The assumption is it would be subclinical infection, not subclinical leprosy. It would trigger an enhanced PEP regimen. The assumption takes into account different efficacy levels.
- **Gangadhar Sunkara:** I'm not sure that the excitement is there in the marketplace. What is the target time to have this tool on the field? We want to meet the 2030 timeline.
  - **Petra Kukkaro:** It will not be commercially attractive. Resource mobilization needs to be flushed out, with different sources of funding. Commercial support would be very valuable. For target timeline: 10 to 12 years to see effects, due to the long incubation period. The standard timeline for diagnostic development is 3 years. And we still need to do groundwork beforehand. Should we do this even though it will not meet the 2030 timeline? What should we invest in the most?
- **Arielle:** We need to manage expectations around the timeframe. We should connect Nienke and Petra because Nienke did work around prioritizing diagnostics. We don't have the tool we need today, so we need to begin to develop it today and move as fast as we can. There's an advocacy component where we need to show that pursuing diagnostics is a conscious decision.

- **Petra Kukkaro:** When prioritizing something else over diagnostics, would it be the same sources of funding that would be taken away? Since WHO has identified that diagnostics are needed in leprosy, are there donors that would want to fund diagnostic development?
- **Wim van Brakel:** Alice is not on the call, but she may have remarked that there is a human rights aspect to this. The clinical capacity of health workers is decreasing in various countries. We want people to be diagnosed earlier. Having a tool that diagnoses at an earlier stage could be promoted from that angle.
  - **Petra Kukkaro:** Ongoing research programs could accelerate diagnostic development. But if we go for regulatory clearances, we need proper clinical validation studies. There is only so much we can accelerate because of the structure of diagnostic development and regulatory hurdles.
- **Bill Simmons:** Is there a use case that demonstrates that a diagnostic would improve patient outcomes? There's urgency if we think about the individual and demonstrate that in five years, people could receive an impact in a low resource setting.
  - **Petra Kukkaro:** Everything we're doing is geared towards a low-resource setting: how it looks in the field and reaches the individual.

## II. Other Updates

- **Bill Gallo:** We request your feedback on what you would like to see in the weekly update emails. We will share a survey with LT members.
- **Mondie Tharp:** We have selected Erik Post as a consultant to refine and further define the Zero Leprosy Country Model. We have selected Carol McPhillips-Tangum to develop the monitoring and evaluation part of the Country Model. Country Model implementation will begin in Côte d'Ivoire on Sunday, April 11. Implementation in Mozambique is scheduled for mid-May at the earliest.