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Working Group on New Diagnostics

Work Plan 2008-2009

The Working Group on New Diagnostics was established in 2001 to promote the development and adoption of new and modified diagnostic products. The Chair of the WG is the Chief Executive Officer of the Foundation for Innovative New Diagnostics (FIND) and the secretariat is provided by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). WG members belong to international organizations, academia, NGOs and industry. Members of the WG have contributed significantly to the advances in the field of TB diagnostics.

The mission of the WG is:

- To advocate and implement research and/or operational activities in pursuit of the development of TB diagnostic tools;
- To collaborate with other elements of the Partnership so as to create synergy and add value to actions taken in pursuit of the aims of the Partnership.

The Working Group on New Diagnostics have supported many major developments in the field of TB diagnostics in recent years, with more than 15 candidate tests in the pipeline, the development of interferon-gamma release assays for detecting TB infection, and the recent endorsement by the WHO of liquid culture systems in low and middle income countries. At least one other diagnostic tool, for the detection of drug-resistant TB, is expected to become available to national TB control programmes in low and middle-income countries in the next 1-2 years.

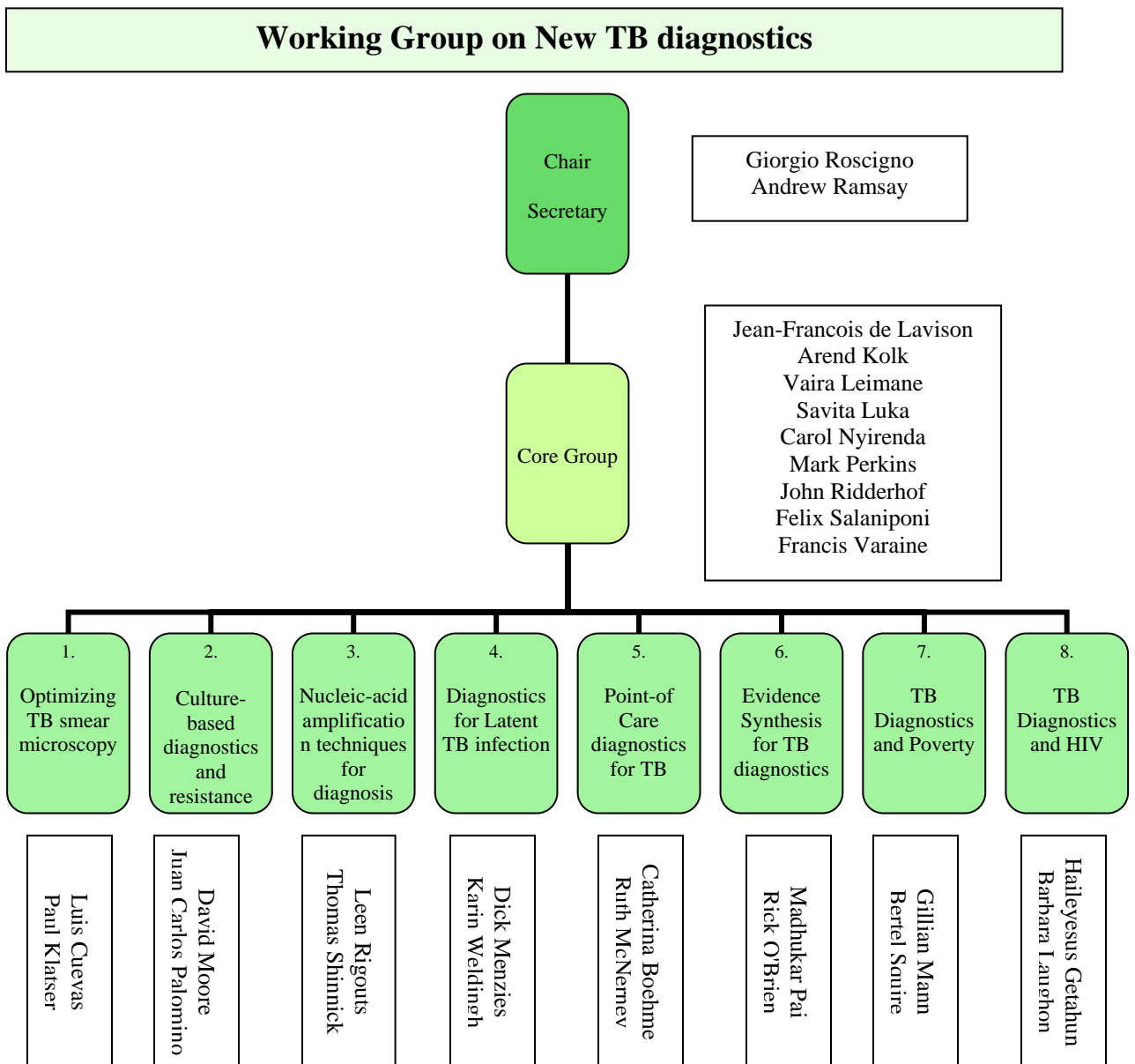
The WG's pipeline of diagnostics in development is now the largest and most promising it has ever been. Because of the increase in the range, speed and intensity of diagnostics development for tuberculosis, the WG is entering a new phase, in which it needs to adapt to reflect these changes. It has recently reorganized itself to this end, by adopting a formal structure based upon a core group of key stakeholder representatives including patients organizations, academia, test developers, diagnostic manufacturers, NTP directors, NGOs, and laboratory capacity strengthening experts. Eight new sub-groups have been launched, each with responsibility for WG activities around particular technologies (eg nucleic acid amplification) or issues relevant to TB diagnostics services (eg. poverty). Each subgroup is headed by two joint co-ordinators. The Structure is as shown in Fig 1. This structure will allow the Working Group to expand its activities while promoting efficiency in its work, and creating synergies with partners both within the New Diagnostics WG and across the other WGs.

After numerous consultations with members of the new core groups and sub-groups a list of priority activities have been drawn up for the WG. The six major priorities are:

1. To intensify collaborations both within the WG on New Diagnostics and with the other WGs of the Stop TB Partnership
2. To develop clear criteria for describing the intended setting for candidate diagnostics tests including the expected level of the health system at which the test may be used, the opportunities for decentralisation of services using the test, its role in special settings such as high HIV prevalence areas or high MDR-TB or XDR-TB prevalence areas
3. To describe an expanded diagnostics pipeline that reflects the explosion in activity aimed at developing new diagnostics for tuberculosis
4. To develop a Scientific Blueprint for the development of TB Diagnostics that will clearly lay out the development and evaluation stages in the value chain of a new diagnostics, and leading to global implementation. This Scientific Blueprint would encourage more test developers to engage in the development of TB diagnostics and would also be an essential step in strengthening national regulatory mechanisms for diagnostics.

5. To develop criteria to place developing technologies at particular stages of the “value chain” of development and evaluation.
6. To work with the STP Retooling Task Force and the Subgroup on Laboratory Capacity Strengthening to promote and facilitate the implementation of new diagnostic technologies and predict the laboratory and health systems capacity required for implementation

Figure 1: Structure and composition of the new Working Group administration



The following activities for 2008-2009 are proposed against each of the main priorities of the Working Group on New Diagnostics together with an approximate cost:

Priority 1: To intensify collaborations both within the WG on New Diagnostics and with the other WGs of the Stop TB Partnership

Activity A: Establishment of the Core Group of the New Diagnostics Working Group and facilitating the Core Group members to take an active role in the development of the WG, providing leadership in working towards the WG goals, and promoting the WG outside of the Stop TB Partnership

Estimated cost: 30,000 USD per annum to fund Core Group workshops and teleconferences, and facilitate attendance of Core Group representative(s) at key external meetings.

Total cost for biennium: 60,000 USD

Activity B: Establishment of Sub-groups within the New Diagnostics Working Group and facilitating the sub-group members to take an active role in developing the Sub-group and working towards their goals.

Estimated cost: 30,000 USD per annum for each sub group to fund Sub-group workshops and teleconferences, and facilitate attendance of Sub-group representative(s) at key external meetings.

Total cost for biennium: 480,000 USD

Activity C: Ensuring that the most suitable/relevant representative(s) of the WG on New Diagnostics can interact with members of other WGs of the Stop TB Partnership, in annual WG meetings as well as expert consultations and workshops around particular issues.

Estimated cost: 20,000 USD per annum.

Total costs for biennium: 40,000 USD

Activity D: Annual all-day meeting of Working Group on New Diagnostics during the Union's World Conference on Lung Health, plus 2 "Meet the Experts" Workshops in the main programme of the conference .

Estimated cost: 100,000 USD per annum to include meeting preparation, implementation, report and follow-up communication and activities. Costs of the participation of key WG members from disease-endemic low and middle income countries.

Total costs for biennium: 200,000 USD

Activity E: Part-time personnel support for secretariat in preparation of New Diagnostics WG materials, and development and maintenance of website.

Estimated cost: 50,000 USD per annum

Total cost for biennium: 100,000 USD

Priority 2: To develop clear criteria for describing the intended setting for candidate diagnostics tests

Activity: To be conducted at the same time as Activity A in Priority Three

Estimated additional cost: 0 USD

Total additional cost for the biennium: 0 USD

Priority 3: To describe an expanded diagnostics pipeline that reflects the explosion in activity aimed at developing new diagnostics for tuberculosis

Activity A: To conduct one workshop in 2008 to describe the expanded pipeline of TB diagnostics under development or evaluation and develop clear criteria for describing the intended setting for candidate diagnostic tests.

Estimated cost: 40,000 USD

Total cost for the biennium: 40,000

Activity B: To update the pipeline in 2009. This will be mainly achieved through e-mail and teleconferences.

Estimated additional cost: 0 USD

Total additional cost for the biennium: 0 USD

Priority 4: To develop a Scientific Blueprint for the development of TB Diagnostics.

Activity: Workshop, consultations, writing, publishing and distributing a Scientific Blueprint for TB Diagnostics Development.

Estimated cost: 80,000 USD per annum

Total cost for the biennium: 160,000 USD

Priority 5: To develop criteria to place developing technologies at particular stages of the “value chain” of development and evaluation.

Activity: To be conducted in association with Priority 4 above.

Estimated additional cost: 0 USD

Total additional cost for the biennium: 0 USD

Priority 6: To work with the STP Retooling Task Force and the Subgroup on Laboratory Capacity Strengthening to promote and facilitate the implementation of new diagnostic technologies

Activity: Participation of WG members in Retooling Task Force and SCLS meetings.

Estimated additional cost: 0 USD

Total additional cost for the biennium: 0 USD

Activity: To develop guidelines for the introduction and sustainable implementation of new diagnostics in partnership with the RTF and SLCS.

Estimated additional cost: 0 USD

Total additional cost for the biennium: 0 USD

REQUESTED BUDGET 2008-2009 – GRAND TOTAL: 1,080,000 USD