Innovation for product development in disease-endemic countries

TDR BUSINESS LINE 4
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<tr>
<td>ANDI</td>
<td>African Network for Drugs and Diagnostics Innovation</td>
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<td>ASTMH</td>
<td>American Society for Tropical Medicine and Hygiene</td>
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<td>BL</td>
<td>Business Line</td>
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<td>DEC</td>
<td>Disease-Endemic Country</td>
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<td>EU</td>
<td>European Union</td>
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<td>FIND</td>
<td>Foundation for Innovative New Diagnostics</td>
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<td>GLP</td>
<td>Good Laboratory Practice</td>
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<td>HDI</td>
<td>Helminth Drug Initiative</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>ICGEB</td>
<td>International Centre for Genetic Engineering and Biotechnology</td>
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<td>IGWG</td>
<td>Inter-Governmental Working Group</td>
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<td>IP</td>
<td>Intellectual Property</td>
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<td>MMV</td>
<td>Medicines for Malaria Venture</td>
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<tr>
<td>NIH-USA</td>
<td>National Institutes of Health - United States of America</td>
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<td>PPP</td>
<td>Public-Private Partnerships</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<td>SAC</td>
<td>Scientific Advisory Committee</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedures</td>
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<td>TDR</td>
<td>Special Programme for Research and Training in Tropical Diseases</td>
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<td>UN</td>
<td>United Nations</td>
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<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WHO/AFRO</td>
<td>World Health Organization Regional Office for Africa</td>
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Overview and highlights

Several factors, including lack of or limited access to health control measures in developing countries, are responsible for the high burden of disease. We still lack vaccines, and diagnostics for most infectious tropical diseases, and available drugs often fail due to resistance, formulation and safety issues. New products are urgently needed, and the perceived lack of commercial return on investment has prevented the pharmaceutical industry from investing in infectious tropical diseases. The emergence of public private partnerships and increasing funding from governments and philanthropic agencies has provided a boost for increased product development for malaria, tuberculosis, HIV and some select neglected diseases. However, the pipelines of some of these PPPs are weak and most of the activities are driven and managed from the North, where the diseases are not endemic. A longer term solution to the product R&D and access crisis will require greater investment and input from the disease-endemic countries (DECs) themselves.

The need expressed through several high level fora to develop capacity for national and regional health innovation in developing countries covering discovery, development, production and commercialization of interventions has received more visibility through the development of the global strategy and plan of action on public health, innovation and intellectual property through World Health Assembly resolution 61.21 (May 2008). This followed extensive intergovernmental negotiations by the member states of the World Health Organization (WHO) as well as previous international and regional calls for increased investment in health and health research in developing countries as a way to achieve sustainable health equity, improve economic development and attain the millennium development goals. A number of recent examples of technology transfer from major pharmaceutical companies to smaller manufacturers in DECs support the concept of local investment in capacity and economic development. Several medium- and low-income countries such as Brazil, India, South Africa, China, Singapore, Kenya, Nigeria, Thailand have considerable capacity for product R&D, that has not been harnessed systematically to promote a coherent product R&D effort for neglected diseases within these countries or regions where they belong. The major challenge lies in coordination of existing research groups in DECs to leverage North-South, South-South and regional R&D collaborative opportunities, access to appropriate technologies, private sector contacts and funding that would empower them to be more competitive and successful.

The African Network for Drugs and Diagnostics Innovation (ANDI), spun off through TDR’s lead discovery business line (see BL3 report), is now forming the core of BL4 activities. It is also seen as a promising model for the implementation of the global strategy and plan of action. Indeed, ANDI was highlighted in the report of the WHO Secretariat on Public Health, Innovation and Intellectual Property to the Executive Board of WHO (January 2009) (Box 1). The support and enthusiasm generated following a very successful ANDI launching in October 2008 at Abuja, Nigeria, has provided the impetus for requests from other regions to initiate similar innovation networks; for example, discussions are ongoing for the establishment of ANDI in Asia-Pacific, Americas (South America) and the Arab States (Middle East) regions.

As part of the recommendations from the Abuja meeting (Annex 2), a Task Force has now been established to develop the strategic and business plan for ANDI. The work and final report of the task force will constitute an important deliverable for TDR and BL4 this year (2009). It will also provide the initial framework for advancing the work of BL4 in supporting other regional ANDIs. Composition and terms of reference for the ANDI task force is presented in Annex 6.3.
1. Context, strategic objectives and framework

1.1. Context

The product R&D pipelines for most of the infectious tropical diseases are weak despite significant recent efforts through PPPs focusing on a number of diseases. Many experts now believe that the long term solution to the product R&D and access crisis will involve greater investment and input from the DECs themselves (Global strategy and plan of action established through WHA 61.21, Call for action at the Bamako ministerial conference 2008).

Over the past 30 years, TDR has supported a number of institutions and investigators in countries around the world including DECs like Brazil, Columbia, Nigeria, Thailand, India and South Africa in developing new technologies for the discovery of novel interventions for infectious diseases such as malaria, leishmaniasis, African sleeping sickness and Chagas disease. Several centres and investigators in developed countries also currently collaborate with TDR and provide important assets in support of innovation and technology transfer to DEC. TDR has established successful public private development projects and discovery networks. Its global convening power through its programs and committee activities allows it to build effective North-South and South-South collaborations. TDR can also build on its previous successful PPP start up experiences (e.g. Medicines for Malaria Venture [MMV], Foundation for Innovative New Diagnostics [FIND]).

We have made the point that the transfer of some of the hits and leads emerging from BL3 to institutions in developing countries for further progression may be key to helping spur innovation in developing countries (See BL3 report and Fig. 1 which illustrates this BL4 strategy). Such is the case at the University of Cape Town in South Africa, where in collaboration with the African Institute for Biomedical Science and Technology in Zimbabwe, researchers are engaged in successful lead optimization efforts. There is also promising work on natural products at the Kenya Medical Research Institute and the National Institute of Pharmaceutical Research and Development in Nigeria, while compound screening activities at the University of Buea in Cameroon and the Theodor Bilharz Research Institute in Egypt are beginning to show positive results. These activities in Africa have supported the initiation of BL4 and ANDI.

The strategy proposed for BL4 and interface with other TDR business lines will bring coherence to the work of TDR in the area of innovation in developing countries including a link to WHO’s global strategy and plan of action.

Also relevant to innovation in developing countries is the work of other TDR business lines including BL1 through links with TropIKA, BL2 (Empowerment) through interface with training, fellowships, support for clinical trails and quality management, BL5 through innovation in vector control, BL6 through interface with ongoing clinical trials in Africa and BL 7 through interaction on diagnostics discovery and evaluation. BL4 will seek proper interface with these BLs to ensure efficient, cost effective and results oriented innovation in developing countries.
“WHO Special Programme for Research and Training in Tropical Diseases and from several African institutions... aims to promote and sustain African-led research and development innovation, and support capacity and infrastructure development in Africa. Network activities to strengthen health innovation in Africa could be a crucial regional contribution towards the implementation of the global strategy and plan of action.”

Excerpt from the report of the WHO Secretariat on Public Health Innovation and IP to the 124th Session of the Executive Board – EB124/16 held in January 2009.

1.2. Strategic objectives

Overall strategic objective:

To facilitate and foster the discovery and development of novel drugs, diagnostics and other products in disease-endemic countries (DECs).

Specific objectives:
1. Define gaps and opportunities for innovative R&D in the South through regional mapping of the R&D landscape
2. Facilitate the design, creation and implementation of innovative regional networks and public-private partnerships in the South dedicated to the discovery, development and delivery of drugs, diagnostics and other health products and technologies in DECs
3. Identify and support competitive discovery and development projects for novel diagnostic tests, drugs and other products for tropical diseases in DECs through targeted calls for application in the South to support projects that will eventually feed into regional networks
4. Facilitate interface with existing North-South/ South-South initiatives, PPPs, biotech/Pharma and regional networks such as ANDI to promote broader South-South and North-South collaboration to enhance technology utilization and transfer
5. Coordinate the development of standard operating procedures (SOPs) and policies for product R&D including legal and IP frameworks to support the discovery and development of pharmaceuticals in DECs.

1.3. Strategic framework

This business line will use a two-phased strategy to implement its objectives (Fig. 1):
1) Leverage and manage interface with relevant TDR business lines and external R&D organizations to initiate product R&D activities in developing countries: This will involve a) proactive interaction with TDR BLs and other organizations involved in product R&D
and capacity building to ensure that relevant ongoing work is linked to BL4 and regional networks, b) implementation of competitive calls for application to identify, and select projects and technologies that will initially be funded under BL4 and subsequently transferred to the regional networks as they become established in the South.

2) Incubate and spin off regional product R&D networks including the promotion of the establishment of biotechnology R&D centres of excellence and public-private partnerships in the South. This will be supported by a) regular identification of gaps and opportunities for innovative R&D in the South through mapping of regional R&D landscape and regular update of the landscape. Establishment of regional database of projects, institutions, investigators and mapping results will be available; b) mechanism to manage R&D portfolios, broker collaborations, foster South-South and North-South partnerships, engage in the management of intellectual property, and implement ethical and policy standards in research in developing countries.

1.4. End-products – 2009–2013

- 4 reports describing the product R&D landscape for Africa, Asia-Pacific, South America and the Arab states (Middle East) made available.
- A database of institutions, investigators and projects from various regions made available (2013)
- 4 regional networks for product R&D in Africa, Asia-Pacific, South America and the Arab states (Middle East) established
- African Network for Drugs and Diagnostics Innovation (ANDI) fully operational and managing product R&D portfolio in Africa
  - Report of the ANDI task force including strategic and business plan for ANDI made available (4Q 2009)
  - ANDI secretariat identified in Africa (1Q 2010)
- Asia-Pacific Network for Drugs and Diagnostics Innovation fully operational and managing product R&D portfolio in Asia-Pacific (2012)
  - Concept document and report of consultation meeting held in China or Singapore (2010)
- Arab-States Network for Drugs and Diagnostics innovation fully operational and managing product R&D portfolio in the Middle East region (2012)
  - Concept document and report of consultation meeting (2010)
- Americas Network for Drugs and Diagnostics innovation fully operational and managing product R&D portfolio in South America (2012)
  - Portfolio of about 10 discovery and development projects in developing countries identified, funded with select promising products transferred to the regional network.
  - 3 health products transitioned from discovery to development (2013)
  - 1 new diagnostic kit developed (2013)
- Interface regional networks (ANDIs) with existing North-South, South-South partnerships to support and enhance technology utilization and transfer including establishment of biotechnology and centres of excellence (2013)
  - Coordinate the development of standard operating procedures and courses for product R&D including legal and IP frameworks to support the discovery and development of pharmaceuticals in DECs
  - 5 centres with SOPs established in Africa, Asia-Pacific, South America and the Arab states (Middle East) with internationally competitive capacity for drugs and diagnostics R&D (2013)
  - 2 centres implementing lead optimization and toxicology studies within developing countries to GLP standards (2013).

The Summary of the objectives, end-products, expected outcomes and indicators for progress is presented in Table 1.
**Overall objective:** To facilitate and foster the discovery and development of novel drugs, diagnostics and other products in disease-endemic countries

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<tr>
<td><strong>Strategic objective 1:</strong> Define gaps and opportunities for innovative R&amp;D in the South through regional mapping of the R&amp;D landscape</td>
<td>Product R&amp;D landscape for Africa, Asia-Pacific, South America and the Arab states (Middle East) available</td>
<td>4 regional consultations implemented and reports made available</td>
<td>ANDI functional in the regions and guided by mapping documents R&amp;D activities focus on priorities, and consider ongoing activities, gaps and opportunities</td>
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<td></td>
<td>Database of institutions/investigators and projects from various regions</td>
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<td><strong>Strategic objective 2:</strong> Facilitate the design, creation and implementation of innovative regional networks and public-private partnerships in the South dedicated to the discovery, development and delivery of drugs, diagnostics and other health products and technologies in DEC</td>
<td>Regional ANDIs (Africa, Asia-Pacific, South America and the Arab states (Middle East) established</td>
<td>Task Force established to develop strategic and business plan (starting with African ANDI) ANDI secretariat identified starting with Africa; website established Strategic and business plan for African ANDI developed, followed by other regions</td>
<td>Sustainable regional ANDI-led networks managing R&amp;D portfolio</td>
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**Table 1. Indicators for End-Products and Outcomes (Till 2013)**
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<td><strong>Strategic objective 3:</strong> Identify and support competitive discovery and development projects for novel diagnostic tests, drugs and other products for tropical diseases in DECs through targeted calls for application in the South to support projects that will eventually feed into the regional networks</td>
<td>3 health products transitioned from discovery to development</td>
<td>Portfolio of projects identified through a transparent review process</td>
<td>Products developed and registered to ensure improved access to quality interventions</td>
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<td></td>
<td>1 diagnostic kit developed and made available</td>
<td>At least 10 centres collaborating and implementing discovery/development projects at the regional level. Managed portfolio of product R&amp;D projects in developing countries</td>
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<td><strong>Strategic objective 4:</strong> Facilitate interface with existing North-South/ South-South initiatives, PPPs, biotech/Pharma and regional networks (ANDIs) to promote broader North-South and South-South collaborations to enhance technology utilization and transfer</td>
<td>Interface regional networks (ANDIs) with existing North-South, South-South partnerships to support and enhance technology utilization and transfer including establishment of biotechnology platforms and centres of excellence</td>
<td>Two centres of excellence or biotechnology platforms supported and accredited</td>
<td>Harmonization of R&amp;D efforts at the regional level</td>
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<td>North-South and South-South partnerships implementing projects and exchanging technologies</td>
<td>Sustainable centres of excellence contributing to local innovation</td>
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<td><strong>Strategic objective 5:</strong> Coordinate the development of standard operating procedures and policies for product R&amp;D including legal and IP frameworks to support the discovery and development of pharmaceuticals in DECs</td>
<td>Centres with standard operating procedures (SOPs) established in Africa, Asia-Pacific, South America and the Arab states (Middle East)</td>
<td>5 centres implementing product R&amp;D using SOPs including GLP standards</td>
<td>Regional centres of excellence performing sustainable R&amp;D within international standards</td>
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<td></td>
<td>Processes for negotiating agreements and managing IP established</td>
<td>10 project agreements concluded</td>
<td>Accessible guidelines and publications. Centres with ethical committees</td>
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2. Key stakeholders and partnerships — roles and responsibilities

BL4 will be implemented with the support of several stakeholders:

i) Technical collaborators identified through calls for applications for example academia and industry;
ii) resource contributors and donors including countries (developed and developing countries), foundations, regional development banks and international organizations, iii) various WHO departments and regional offices including the WHO secretariat for Public Health, Innovation and Intellectual Property and control departments, iv) research institutions including academia, pharma, animal health companies and public-private partnerships, v) countries, Ministries of Health, Science and Technology, vi) traditional healers. This range of stakeholders is reflected in the composition of the ANDI Task Force (Annex 6.3)
3. Implementation plan 2008–2013 and progress

3.1A. The 2008–2013 implementation plan

As stated above this business line will use a two-phased strategy to implement its objectives through product R&D activities in developing countries based on the ANDI Concept (Fig. 1). The activities and end-products till 2013 are mentioned in sub-paragraph 1.4 and Table 1. Specific activities, plan and deliverables for 2009–2010 biennium are presented in Annex 6.1.

3.1B. Progress and key achievements

3.1B-A. Define gaps and opportunities for innovative R&D in the South through regional mapping of R&D landscape.

- Product R&D landscape for Africa mapped and made available through publication and websites (This was done as part of the initiation of ANDI (http://www.who.int/tdr/news-events/news/pdf/ANDI-rd-landscape-abstracts.pdf).

In summary, the report shows that significant but isolated product discovery and development activities are ongoing in Africa, and to achieve coherent and sustainable product innovation, greater effort is needed to bring together the various groups working in this area to join forces, share lessons, and implement a more coordinated approach to health R&D and innovation in Africa (Fig. 2).

Although the report identified gaps in capacity, financing and infrastructure, it reveals that current activities and existing capacity and infrastructure can be leveraged to support significant health product R&D innovation work in Africa. The report also identified successful product R&D activities that have resulted in commercialized products. Several experts interviewed expressed the desire for greater emphasis in research to support the use of traditional medicines and better protection and management of local knowledge including intellectual property. The report identified some successes, gaps, challenges and opportunities that is now helping in the shaping the work of ANDI and BL4.
3.1B-B. Facilitate creation of regional networks and public-private partnerships in the South dedicated to innovation for discovery and development of drugs, diagnostics and other health products and technologies in DECs

Background information and activities that led to establishment of ANDI in 2008 and the transfer of ANDI activities to BL4 has been described in BL3 report. Achievements in the past two months and plans for the rest of 2009 are highlighted below:

• Implementation of the recommendations from the 1st ANDI meeting at Abuja has started with the establishment of the ANDI Task Force charged with specific terms of reference and responsibilities related to providing the draft strategic blueprint for ANDI including business plan, funding, and appropriate R&D model. The composition of the task force and full terms of reference is in Annex 6.3.

• The first meeting of the ANDI task force was held in Geneva on February 10, 2009. The outcomes from the meeting include: the establishment of timelines for the work and deliverables of the task force, approval of the call to identify a business development consultant to support the task force in the development of the strategic and business plan for ANDI, agreement to hold the next face to face meeting of the task force at the African Development Bank in Tunis and the 3rd meeting at the WHO/AFRO regional office in Brazzaville. The potential scope of work, options for the organizational structure of ANDI as well as selection criteria for African country to host the Secretariat were also discussed. It was agreed that the report of the task force will be presented at the 2nd ANDI stakeholders meeting to be held in South Africa at the Medical Research Council, Cape Town. The full report of the 1st ANDI Task Force meeting is being finalized.

• Discussion and planning for the initiation of Asian and Middle East ANDIs

3.1B-C. Identify and support competitive discovery and development projects for novel diagnostic tests, drugs and other products for tropical diseases in DECs through target calls for application in the South to support what will eventually feed into a regional network or partnerships once established

• Progress on this objective will be reported in 2010/2011

3.1B-D. Facilitate interface with existing North-South/South-South initiatives, PPPs, biotech/Pharma and regional networks such as ANDI to promote broader South-South and North-South collaboration to enhance technology utilization and transfer

• The successful interface between the North-South drug discovery network of BL3 and BL4 through ANDI is an example of excellent interfacing activity that can be leveraged to support innovation in developing countries. The plan is for BL4 to intensify interface with other BLs and existing regional activities

3.1B-E. Coordinate the development of standard operating procedures and policies for product RG-D including ethical, social, legal and IP frameworks to support the discovery and development of pharmaceuticals in DECs

• Progress on this objective will be reported in 2010/2011
3.2. Implications of progress/delays and global context changes on 2008-2013 plans

As shown in Fig. 3, a significant innovation gap remains despite some ongoing activities in drug discovery and development activities for malaria, tuberculosis and some neglected diseases undertaken through partnerships by industry and academia.

The picture is even worse for diagnostics where very little discovery activities are ongoing (Fig. 4). In addition to recent interests in promoting innovation, for example through the Gates Grand Challenges and other funding institutions, a major change in the past two years regarding intergovernmental support for innovation has come through the IGWG process that resulted in the approval of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The emphasis now placed on promoting innovation in developing countries is a forward-looking agenda that could contribute to sustaining long term access to health products within these countries. ANDI is a practical approach initiated by TDR in implementing R&D initiatives in developing countries which is hoped to attract more attention from the international community in the coming months and years.

BL4 is consistent with this trend and has helped to inform parts of the IGWG discussions and initiation of ANDI. As highlighted above, the WHO Secretariat identified ANDI in its report to the Executive Board of WHO in January 2009 as example of progress towards the implementation of the Global strategy and plan of action. This recognition is also reflected in the mini-business plan being developed by TDR (with support from McKinsey & Co) as its response to the global strategy and plan of action of the IGWG.

Fig. 3. Translational innovation gap in drug discovery for infectious tropical diseases

Fig. 4. Translational innovation gap in diagnostics discovery for infectious tropical diseases
3.3. Specific activities for 2009

Specific activities for each of the BL4 objectives have been identified for 2009 and 2010 in Annex 6.1. Some activities for 2009 are highlighted below:

3.3.1. Revise BL4 business plan in the line with objectives and incorporate input from STAC and StANDIng committee (1Q 2009). In this context, it should be mentioned that McKinsey and Co. a business development consultant, is now conducting a study, on the innovation capacity within TDR, to inform the development of mini-business plan requested by TDR’s Joint Coordinating Board in response to the global strategy and plan of action. BL4 and other BLs are providing some material towards the development of this mini-business plan.

3.3.2. Continued work on ANDI including managing the ANDI Task Force charged with the establishment of the operational and business plan

3.3.3. Implement consultation meetings for the Asian and Middle East ANDI in collaboration with relevant TDR BLs including BL2, BL3, BL6 and BL7

3.3.4. Present BL 4 to STAC with a view to establishing an independent SAC for BL4 by 4Q 2009
4. BL leverage, contributions to empowerment and stewardship and synergies with TDR business lines

4.1. Leverage

4.1.1. It was suggested that the transfer of some of the hits and leads emerging from the BL3 network activities to institutions in developing countries for further progression may be key in helping spur innovation in developing countries. Indeed, this is already proving to be the case, for example, through a successful lead optimization work at the University of Cape Town, in South Africa in collaboration with the African Institute for Biomedical Science and Technology in Zimbabwe. Also, support for work at the Kenya Medical Research Institute and the National Institute of Pharmaceutical Research and Development in Nigeria on natural products as well as new screening centres in Africa such as the University of Buea in Cameroon and the Theodor Bilharz Research Institute in Egypt are beginning to show positive results. These activities in Africa have provided the framework for a focused products innovation platform within Africa. As exemplified by ANDI, TDR is now leveraging partners and the North-South network to kickstart substantial innovation activities in developing countries.

4.1.2. Access to leading experts willing to serve in the ANDI Task Force at little or no cost is a significant leverage.

4.1.3. Mapping exercise was largely performed through support from African scientists at little or no cost.

4.1.4. Strong link of the ANDI initiative to the WHO’s global strategy is providing support and has helped in additional technical and political support for this activity, for example, the report of the WHO secretariat to the Executive Board that highlights ANDI, the mix of various stakeholders in the ANDI Task Force.

4.2. Contribution to overall empowerment and stewardship and synergy with TDR business lines

4.2.1 Contribution of BL4 to stewardship and empowerment.

As indicated earlier, this BL4 is at the heart of supporting and advocating for a pivotal role of DECs in product R&D. Meetings and invited lectures as part of promoting innovation are in Annex 6.4. The work is supporting significant stewardship and empowerment functions in the South; for example, through strong mobilization and participation of African scientists and institutions in the ANDI initiative. The feeling of ownership and participation of Africans is apparent and demonstrates their pivotal role. The ANDI task force membership is comprised of a significant number of African experts. The same is envisaged for other regional networks. Other examples of Empowerment function are the training of developing country researchers on innovation and exploring natural products as a source of leads in developing countries.
4.2.2. Synergy with work of other BLs

As discussed, BL4 is in a unique position to interface and harness the outcomes from all the TDR business lines to support innovation in developing countries; for example, through ANDI. BL1, BL2 and BL7 worked with BL3 in launching ANDI and initial discussions on Asian ANDI. The Helminth Drug Initiative (HDI), established in 2006 within BL3 to address the dearth of anthelmintic drug discovery and development activities, will also feed products into BL4.

The two-phased strategy proposed for BL4 and the link with other TDR business lines will enhance the work of TDR in the area of innovation in developing countries including a link to WHO's global strategy and plan of action.
5. Critical issues and suggested solutions

The following questions were identified by STAC last year about BL4 and are now being addressed:

1) Improved business plan for BL4: this report has now strengthened the initial draft business plan for BL4 with clearer objectives, deliverables and concrete activities. Also elements of this report are feeding into the mini-business plan being developed for innovation through McKinsey and Co.

2) The budget for BL4 was initiated through the ANDI activities of BL3. ANDI, however, is now fully integrated into BL4’s activities for 2009. The hope is that BL4 will get more funds and personnel this year and in the coming years to implement the highly promising ANDI activities. A minimum of two professional and two support staff is needed for BL4 this year to support planned ANDI activities.
6. Annexes


**Overall objective:** To facilitate and foster the discovery and development of novel drugs, diagnostics and other products in disease-endemic countries (DECs).

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<tr>
<th>Components of objectives</th>
<th>Proposed activities/milestones</th>
<th>Deliverables and end-products</th>
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| 1. Define gaps and opportunities for innovative R&D in the South through regional mapping of R&D landscape. | • Update mapping of product R&D landscape in Africa (2009)  
• Initiate mapping of the R&D landscape in other regional ANDIs (2009/2010)  
• Build on the R&D landscape documents to initiate the development of a database of projects, institutions and investigators in Africa and the regional ANDIs (2010) | • Updated map of the products R&D landscape in Africa  
• Report on R&D landscape for one regional ANDI  
• Database of projects, institutions and investigators in Africa and other regions |
| 2. Facilitate the creation of regional networks and public-private partnerships in the South dedicated to innovation for discovery and development of drugs, diagnostics and other health products and technologies in DECs. | • Organize consultative meetings in the various regions for the establishment and framework of other regional ANDIs (2009/2010)  
• Launch ANDI for Asia-Pacific region (early 2010) | • Consultation meetings held and reports available for Asia and Middle East  
• ANDI for Asia-Pacific region launched |
| 3. Identify and support competitive discovery and development projects for novel diagnostic tests, drugs and other products for tropical diseases in DECs through target calls for applications in the South to support what will eventually feed into a regional network of partnerships once established. | • Establish SAC for project review (2010)  
• Initiate a call for applications to identify promising projects in Africa (2009)  
• Establish criteria for project review and monitoring (2009)  
• Review and selection of projects by SAC (2010) | • Portfolio of ~6 discovery and development projects in developing countries identified, funded and managed within the framework of BL4-ANDI |
### Components of objectives

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<th>Objectives</th>
<th>Proposed activities/milestones</th>
<th>Deliverables and end-products</th>
</tr>
</thead>
</table>
| 4. Facilitate interface with existing North-South/South-South initiatives, PPPs, biotech/Pharma and regional networks (ANDIs) to promote broader North-South and South-South collaborations to enhance technology utilization and transfer | • Foster closer interface between BL4 and other TDR BLs  
• Foster sharing of lessons as the different regional ANDIs are established  
• Participation of different stakeholders in ANDI meetings | • Leads transferred to centres in the region  
• Technical support provided through other BLs for establishment of ANDIs |
| 5. Coordinate the development of standard operating procedures and policies for product R&D including legal and IP frameworks to support the discovery and development of pharmaceuticals in DECs | • Initiate the transfer of available and relevant SOPs for discovery and development including GLP and GCP processes to DEC institutions (2009) | • 2 centres implementing SOPs in developing countries  
• 1 centre in DEC with the capacity for target selection/validation, screening  
• 1 centre in DEC implementing lead and optimization studies for development as novel drugs or diagnostics for TDR target diseases |
| Other specific stewardship/empowerment/coordination activities linked to above objectives | • Establish SAC for BL4  
• Promote innovation in the South at international meeting (2009/2010)  
• Transfer of discovery and development techniques and SOPs from TDR BLs to centres in the South  
• Fellowships and training for scientists from developing countries through North-South and South-South network activities  
• Continue work on ANDI including managing the ANDI Task Force charged with the establishment of the strategic and business plan for ANDI (Africa) (2009)  
• Present report of the ANDI (Africa) Task Force at the 2nd ANDI Meeting (2009) | • BL4 SAC established & meeting held (2009)  
• ANDI Task Force (Africa) report/business plan (2009)  
• African Secretariat identified (2010)  
• Managed portfolio of projects in the South  
• 2 fellows trained (2010)  
• 2 meetings organized to promote innovation (2010)  
• Definite plans for launch of other regional ANDIs (2009–2010) |
6.2. Summary of discussions and recommendations from ANDI inaugural meeting (6–8 October 2008, Abuja, Nigeria)

- A small working committee (Task Force) should be urgently established with proper representation of African stakeholders and other partners to collate suggestions and recommendations from all ANDI documentations and Abuja meeting. The task force will be tasked with specific terms of reference and responsibilities related to providing the draft strategic blueprint for ANDI (policy, strategy, business plan including governance), funding, and appropriate R&D model considering existing virtual R&D models.
- The draft strategic blueprint will be shared with the community as it is developed and will be presented for review at a subsequent meeting of ANDI, with a target date of 4Q 2009.
- Additional mandate for such committee include:
  - Consideration for a definitive Africa based Secretariat. The idea of a rotational Secretariat to be explored.
  - Suggest an interim secretariat that will be hosted by TDR until ANDI agenda is mature.
  - Others suggested that the blueprint for ANDI be finalized first prior to the selection of the centre to host the Secretariat.
  - Consideration for different languages used in Africa.
  - ANDI to urge government support for R&D of defined priorities and promising deliverables.
  - ANDI to urge government to invest counterpart funding to match external funding.
  - ANDI to engage in advocacy for product R&D at all levels.
  - Establish website and interactive Community of Practice for ANDI.
6.3. ANDI Task Force (terms of reference and membership)

Following the recommendations from over 200 participants from 21 countries at the inaugural meeting of the African Network for Drugs and Diagnostics Innovation (ANDI), held at Abuja (on 6-8 October 2008), a Task Force has now been constituted to implement the recommendations agreed at the ANDI meeting. The full ANDI Meeting Report is attached for your reference.

The Terms of Reference for the Task Force are as follows:

1. Collate and review all documentation on ANDI from February 2008, when the idea was put forward by TDR to African scientist and institutions, to the present. These documents include: the ANDI concept paper, meeting brochure, the African R&D mapping document and book of abstracts.

2. Review the recommendations from the Abuja meeting as contained in the meeting report.

3. Review the global strategy and plan of action on public health, innovation and IP as well as other relevant strategies, documents as well as declaration by African governments in support of local R&D.

4. On the basis of the above documents, work with an expert business development consultant to develop a strategic and business plan for ANDI. The strategy for the implementation of ANDI should clearly define the following:
   a. The mission, vision and objectives of ANDI which takes into consideration the current product R&D, manufacturing, and registration landscape in Africa and globally.
   b. The scope of work and focus of ANDI in terms of product R&D, disease coverage and advocacy considering final report of the ANDI meeting and the unique situation of the African continent.
   c. The governance and structure for ANDI including the organizational structure and implementation plan along the lines of a cost and technically efficient, and accountable virtual R&D model that is appropriate for the African continent.

5. Identify a definitive ANDI headquarters/secretariat in Africa while considering the offer made by the Nigerian government at the ANDI launch meeting to host ANDI secretariat.

6. Hold regular meetings face to face and communications through e-mails or by telephone. Face to face meetings are expected to occur 3 times within the first year, with additional meetings as needed to finalize the documentation for presentation at the next ANDI meeting in 4Q 2009.

7. The deliverables from the Task Force will include a business and strategic plan covering all elements of the organizational structure and implementation plan with budget, as well as scope of work for ANDI, as specified above.

8. The work of the Task Force is expected to start in January 2009, upon notification of all members, and to end not later than 1Q 2010, after the business/operational plan including governance and headquarters/secretariat has been agreed and presented at the next ANDI meeting.
Composition of the ANDI Task Force:

1. Dr Tom Mboya-Okeyo (Kenyan Ambassador to UN Geneva) - Chair of the Task Force
2. Dr Alex Ochem (ICGEB - South Africa), Secretary of the Task Force
3. Dr Uford Inyang, Director General, National Institute for Pharmaceutical Research and Development, Nigeria
4. Dr Anthony Mbewu, Director, Medical Research Council of South Africa
5. Dr Sanaa Botros, Theodor Bilharz Research Institute, Cairo, Egypt
6. Dr Anastasia Guantai, Kenya Medical Research Council
7. Dr Tshinko Ilunga, Manager Health Division, Human Development Department, African Development Bank
8. Dr Peter Atadja, Novartis (representing Africans in Diaspora)
9. Dr Tachi Yamada, President Global Health, Gates Foundation (or representative) - tbc
10. Dr Mark Walport, Executive Director, Wellcome Trust (or representative)
11. Representative from Fogarty International (NIH, USA)
12. Representative of the EU
13. WHO/TDR Secretariat:
   a. Dr Robert Ridley, TDR Director
   b. Dr Solomon Nwaka, Leader, Drug Discovery and Innovation (local point for ANDI and Task Force activities)

Please refer to Annex 4 for meetings of the ANDI Task Force in 2009.
6.4. List of meetings, conferences planned for 2009

- 1st ANDI Task Force meeting 10 February 2009
- ANDI Task Force tele/videoconferences (23 March, 6 July, 7 Sep, 28 Sept and 7 Dec 2009, 14:00 GMT)
- 2nd ANDI Task Force meeting 7-8 May 2009 at the African Development Bank, Tunis, Tunisia
- 3rd ANDI Task Force meeting 3–4 August 2009 (Brazzaville, DRC)
- Second stakeholder ANDI meeting in Africa: October 2009, Medical Research Council, Cape Town, South Africa
- Consultative meetings for Asia and Middle East ANDIs (China 1Q 2009 and Dubai 3Q 2009)
- ANDI will be highlighted at planned international meetings in November 2009 including the Annual Meeting of the ASTMH, Washington, DC, and MIM in Tanzania