Innovation for product development in
disease endemic countries
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<th>Abbreviation</th>
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<tbody>
<tr>
<td>AFRO</td>
<td>WHO Regional Office for Africa</td>
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<td>ANDI</td>
<td>African Network for Drugs and Diagnostics Innovation</td>
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<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<td>ASTMH</td>
<td>American Society of 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>GMP</td>
<td>Good manufacturing practice</td>
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<td>GSPOA</td>
<td>Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property</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>Intergovernmental Working Group</td>
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<td>IP</td>
<td>Intellectual property</td>
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<td>LOC</td>
<td>Local organizing committee</td>
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<td>MMV</td>
<td>Medicines for Malaria Venture</td>
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<td>NAPPSA</td>
<td>Nigerian Association of Pharmacists and Pharmaceutical Scientists in the Americas, Inc.</td>
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<td>NDI</td>
<td>Network for Drugs and Diagnostics Innovation</td>
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<td>NIH</td>
<td>National Institutes of Health</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>Strategic and Scientific Advisory Committee</td>
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<td>SBP</td>
<td>Strategic and business plan</td>
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<td>SOP</td>
<td>Standard operating procedures</td>
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<td>STAC</td>
<td>Scientific and Technical Advisory Committee</td>
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<td>TDR</td>
<td>The Special Programme for Research and Training in Tropical Diseases</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Overview and highlights

Several factors, including limited or no access to effective health tools (drugs, vaccines, diagnostics and insecticides), are responsible for the high burden of disease in developing countries. Tools often fail due to resistance, formulation, compliance and safety issues. New products are urgently needed, but 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 (PPPs) and increasing funding from governments and philanthropic agencies has led to 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 developed countries where the targeted diseases are not endemic. A longer term solution to the product research and development (R&D) and access crisis will require greater participation, leadership, investment and ownership by the disease endemic countries (DECs) themselves. The need to support local research and development efforts to tackle local health needs in developing countries has been recommended and documented by several high level reports. The WHO’s Commission on Macroeconomics and Health (2001) pointed out that investing in R&D capabilities could play a critical role in improving health outcomes and promoting economic development. Other recent regional and international reports and declarations, such as the UN Millennium Project 2005 and the Algiers Declaration of 2008, have reinforced these recommendations.

These events provided the backdrop to the recent intergovernmental process that led to the establishment of the global strategy and plan of action on public health, innovation and intellectual property (GSPOA) adopted through World Health Assembly Resolution (WHA 61.21 in 2008 and 62.16 in 2009). In this context the regional innovation networks, exemplified by the African Network for Drugs and Diagnostics Innovation (ANDI) being implemented by BL4, present a unique opportunity to support the implementation of these actions in developing countries. ANDI obtained substantial recognition in 2009 by the World Health Assembly (WHA 62.16) as a key initiative aimed at supporting and promoting African-led health product innovation for the discovery, development and delivery of drugs and diagnostics.

ANDI was conceived in early 2008 under TDR’s lead discovery Business Line 3, with the concept launched in Abuja, Nigeria in October 2008 to the enthusiastic support of hundreds of African scientists and institutions, Africans in the diaspora and non-African scientists, policy-makers and others. This enthusiasm has helped propel the rapid evolution and achievements of ANDI to date (Fig. 1). As part of the recommendations from the Abuja meeting, a task force was established to develop the strategic and business plan for ANDI, covering its scope of work, organizational and implementation plan. The report of the task force, as well as the strategic and business plan for ANDI, was presented and unanimously adopted at the 2nd ANDI stakeholder’s meeting in Cape Town, South Africa in October 2009. The meeting was attended by over 200 participants across Africa, including ministers of health and science and technology. The endorsement of this plan is a major milestone for ANDI, TDR and the GSPOA.

The mission of ANDI is “To promote and sustain African-led health product innovation to address African public health needs through assembly of research networks, and building of capacity to support human and economic development.”
The vision of ANDI is “To create a sustainable platform for R&D innovation in Africa to address Africa’s health needs.” This vision is applicable to other regions and, as such, ANDI is seen as a promising model for the implementation of the GSPOA.

The establishment of the Asian and Americas (South American) Network for Drugs and Diagnostics Innovation (Asian NDI, South American NDI) has also been initiated as part of BL4 activity. A three-pronged approach has been developed for the establishment of the Asian NDI that provides independent R&D mapping for China, India and the 10 member countries of the Association of Southeast Asian Nations (ASEAN). These countries will be brought together at a later stage to discuss the framework for implementation of the Asian NDI. The Chinese network was launched at a major meeting in Shanghai in October 2009, where the results from the initial mapping activity in China were reviewed. This was followed that month with a brainstorming meeting of the ASEAN countries in Manila to plan for the start of the R&D landscape mapping for the ASEAN countries. A similar meeting and mapping is expected to be initiated in India early in 2010, along with a broader Asian meeting to discuss the feasibility of a central Asian NDI. For South America, a brainstorming meeting was organized in Panama in September 2009. In all cases, discussions and meetings are being held in collaboration with the WHO regional offices.

Summary of key achievements and highlights for 2009

The major achievement in 2009 was the timely and successful implementation of the ANDI task force activities which culminated in the development of the strategic and business plan (SBP) for ANDI and, ultimately, the endorsement of the plan at the second ANDI stakeholder’s meeting held from 5-7 October 2009 at the Medical Research Council in Cape Town, South Africa.
1. Context, strategic objectives and framework

1.1 Context and rationale

The product R&D pipelines for most of the infectious tropical diseases are weak, despite recent significant efforts through PPPs focusing on specific diseases. Many experts now believe that an important part of the solution to the high disease burden and product access crises in developing countries lies in empowering local R&D to tackle local health needs. The WHO’s Commission on Macroeconomics and Health (2001) argued that investing in R&D capabilities could play a critical role in improving health outcomes and promoting economic development. A number of recent examples of technology transfer from major pharmaceutical companies to smaller manufacturers in developing countries show that the concept of local investment in capacity and economic development is feasible. Several medium- and low-income countries (such as Brazil, India, South Africa, China, Singapore, Kenya, Nigeria and Thailand) have considerable capacity for product R&D which has not been harnessed systematically to promote a coherent effort for diseases that are predominant in these countries or within the regions to which they belong. The major challenge lies in the identification and coordination of existing R&D groups (public and private) to support intracountry or regional R&D collaboration, including sharing of information, technologies, funding and establishment of partnerships. This intraregional collaboration will further strengthen international south–south as well as north–south collaborations.

This awareness helped to initiate the recent intergovernmental process that led to the establishment of the GSPOA adopted through a World Health Assembly Resolution (WHA 61.21 in 2008 and 62.16 in 2009). In this context the regional innovation networks, exemplified by ANDI (being implemented by BL4), present a unique opportunity to support the implementation of these actions in developing countries. ANDI obtained substantial recognition in 2009 by the World Health Assembly (WHA62.16) as a key initiative aimed at supporting and promoting African-led health product innovation for the discovery, development and delivery of drugs and diagnostics.

The proposed regional innovation networks are unique, compared with other existing product development initiatives. This uniqueness is illustrated by the following features of ANDI:

• African-led – projects driven by local investigators;
• African-oriented – agenda aligned with local priorities;
• sustainable – backbone created for product innovation; adapted to evolving health needs and moving products along the R&D value chain;
• emphasis on internal and external collaborations – strong south–south and north–south collaborations.

Over the past 30 years, TDR has supported a number of institutions and investigators in countries around the world, including Brazil, Columbia, Nigeria, Thailand, India and South Africa, to develop new technologies for the discovery of novel interventions for infectious diseases such as malaria, leishmaniasis, African sleeping sickness and Chagas disease. TDR has established successful PPPs and networks focusing on product discovery and development. Its global convening power supports the building of effective north–south and south–south collaborations.

This business line provides for the transfer of some of the leads emerging from the lead discovery business line (BL3) to institutions in developing countries.
countries for further progression. Researchers at the University of Cape Town in South Africa, in collaboration with the African Institute of Biomedical Science and Technology in Zimbabwe, are engaged in successful lead optimization efforts. There are ongoing medicinal chemistry and screening efforts at the University of São Paulo using TDR lead compounds, and promising work on natural products at the Kenya Medical Research Institute and the National Institute for Pharmaceutical Research and Development in Nigeria. Compound screening activities at the University of Buea in Cameroon and the Theodor Bilharz Research Institute in Egypt are beginning to show promising results. These activities provide support for the regional networks for innovation now being implemented by BL4.

The BL4 strategy (see Fig. 2) takes advantage of not only the available leads from BL3, but other TDR business lines, and a strong link to the WHO's GSPOA. The other TDR business lines interfacing with BL4 include BL1 through prioritization of research and links with TropIKA; BL2 (empowerment) through training, fellowships, support for clinical trials and quality management; BL5 through vector research; BL6 through interface with clinical trials; and BL7 through interaction on diagnostics evaluation. BL4 will interface with these business lines to ensure efficient, cost-effective and results-orientated innovation in developing countries.

1.2 Strategic objectives

The overall strategic objective is to facilitate the discovery and development of novel drugs, diagnostics and other products in DECs.

Strategic objectives:

1. Define gaps and opportunities for innovative R&D in the south through regional mapping of the R&D landscape and capabilities.

2. Facilitate the design, creation and implementation of regional innovation networks in the south, dedicated to the discovery, development and delivery of drugs, diagnostics and other health products and technologies in DECs.

3. Support the discovery and development of novel diagnostic tests, drugs and other products for tropical diseases in DECs through targeted calls for application that will eventually feed into regional networks.

4. Coordinate the development of standard operating procedures (SOPs) to support the discovery and development of pharmaceutical products in DECs.

5. Facilitate interface with existing initiatives, PPPs, biotechnology and pharmaceutical companies and regional networks such as ANDI to promote broader south–south and north–south collaboration to enhance technology utilization and transfer.

1.3 Strategic framework

This business line will use a two-phased strategy to implement its objectives (Fig. 2):

1. Incubate and spin off regional innovation networks, including support for the establishment of R&D centres of excellence and PPPs in developing countries. This will be supported by: a) regular assessment of gaps and opportunities for innovative R&D in DECs through the mapping of the regional R&D landscape and the establishment of accessible databases with mapping results and lists of projects, institutions and investigators; b) brokerage of collaborations, including support for south–south and north–south partnerships, management of intellectual property, and establishing SOPs for product R&D in developing countries.

2. Leverage and manage the interface with relevant TDR business lines and external R&D organizations to support product R&D activities in developing countries. This will involve: a) close interaction with TDR business lines and other organizations involved in product R&D, and capacity-building to ensure synergy with BL4 and regional networks; b) implementation of competitive calls for grant applications 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 developing countries.
### 1.4 End-products (2010–2013)

**Strategic objective 1:** define gaps and opportunities for innovative R&D in the south through regional mapping of the R&D landscape and capabilities.

- Four reports describing the R&D landscape for Africa, Asia, South America and the Arab states (Middle East) made available.
- A database of institutions, investigators and projects from various regions made available (2013).

**Strategic objective 2:** facilitate the design, creation and implementation of regional innovation networks in the south, dedicated to the discovery, development and delivery of drugs, diagnostics and other health products and technologies in DECs.

- Four regional networks for product R&D in Africa, Asia, South America and the Arab states (Middle East) established.
  - ANDI fully operational and managing product R&D portfolio in Africa (2012) – timelines for implementation and transitioning ANDI to Africa can be found in Fig. 3. This includes the following actions:
    - Establishment of ANDI board and launching it at third stakeholder’s meeting in Nairobi (Q4 2010).
    - Identification of initial ANDI projects through call for application (Q4 2010).
    - Development of ANDI website and database (2010).
  - Asian Network for Drugs and Diagnostics Innovation fully operational and managing product R&D portfolio in Asia (2012).
    - China NDI – report of China consultation and R&D mapping made available (Q4 2010).
    - India NDI – R&D mapping initiated (Q1 2010).
    - ASEAN NDI – report of consultation and R&D mapping made available (Q4 2010).
    - Broad Asian meeting held with agreement on structure of the Asian network (2010).
    - Strategic and business plan available (2011).
  - Arab States Network for Drugs and Diagnostics Innovation – established in the Middle East region (2013).
    - Informal consultations and initiation of R&D landscape mapping (2010).
    - Strategic and business plan developed (2012).
  - Americas Network for Drugs and Diagnostics Innovation established in South America (2013).
    - Informal consultations and initiation of R&D landscape mapping (2010).
    - Strategic and business plan developed (2012).


Strategic objective 3: support competitive discovery and development projects for novel diagnostic tests, drugs and other products for diseases in DECs through targeted calls for application that will eventually feed into regional networks.

- Portfolio of about five discovery and development projects in developing countries funded and managed, including transfer of promising projects to the regional network.
  - Four projects transferred to regional networks (2013).
  - One health product transitioned from discovery to development (2013).
  - One new diagnostic kit developed (2013).

Strategic objective 4: coordinate the development of SOPs to support product R&D in DECs.

- Support the development of SOPs and courses for product R&D, including legal and intellectual property frameworks to support the discovery and development of pharmaceutical products in DECs.

- Five centres implementing SOPs for drugs and diagnostics R&D in Africa, Asia, South America and the Arab states (Middle East) (2013).

Strategic objective 5: facilitate interface with existing initiatives, PPPs, biotechnology and pharmaceutical companies and regional networks such as ANDI to promote broader south–south and north–south collaboration for technology utilization and transfer.

- Two centres of excellence or biotechnology platforms supported and accredited.
- Collaboration between regional networks (NDIs) and existing north–south, south–south partnerships to support and enhance technology utilization and transfer, including establishment of biotechnology and centres of excellence (2013).

A 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 DECs

|---------------------|---------------------|----------------------------|-----------------------------|
| **Strategic objective 1:** define gaps and opportunities for innovative R&D in the south through regional mapping of the R&D landscape and capacities | - Four reports on the R&D landscape and capacity for Africa, Asia, South America and the Arab states (Middle East) available  
- A database of institutions/Investigators and projects from various regions | - Initiation of landscape mapping for Asia, South America and Middle East through consultation meeting  
- Meetings to review mapping results for Africa, Asia, South America and the Arab states (Middle East) implemented and reports made available (2012) | - Regional networks such as ANDI functional and guided by mapping documents that highlight priorities, gaps and opportunities |
| **Strategic objective 2:** facilitate the design, creation and implementation of regional innovation networks in the south dedicated to the discovery, development and delivery of drugs, diagnostics and other health products and technologies in DECs | - Four regional or subregional networks (Africa, Asia-Pacific, South America and the Arab states (Middle East) established  
- ANDI fully operational and managing product R&D portfolio in Africa | - ANDI board established (Q4 2009)  
- ANDI secretariat identified in Africa (Q4 2010)  
- Asia Network for Drugs and Diagnostics Innovation fully operational and managing product R&D portfolio in Asia-Pacific (2012); report of mapping and consultation meeting held (Q4 2010)  
- Arab States Network for Drugs and Diagnostics Innovation established in the Middle East region (2012); informal consultations and initiation of R&D landscape mapping (2010); report of mapping of R&D landscape (2012)  
- Americas Network for Drugs and Diagnostics Innovation initiated in South America (2012); informal consultations and initiation of R&D landscape mapping (2010); report of mapping of R&D landscape (2012) | - Sustainable regional networks managing R&D portfolio |
### TABLE 1 (CONT). BL4 INDICATORS FOR END-PRODUCTS AND OUTCOMES

|--------------------|---------------------|-----------------------------|-----------------------------|
| **Strategic objective 3:** support the discovery and development of novel diagnostic tests, drugs and other products for tropical diseases in DECs through targeted calls for applications in the south to support projects that will eventually feed into the regional networks | • Four projects transferred to regional networks (2013)  
• One health product transitioned from discovery to development  
• One diagnostic kit developed and made available | • Managed portfolio of about five discovery and development projects in developing countries identified through a transparent review process  
• Funded promising products transferred to the regional network | • Products developed and registered to ensure improved access to quality interventions |
| **Strategic objective 4:** coordinate the development of standard operating procedures to support product R&D in DECs | • Five centres implementing product R&D using SOPs, including good laboratory practice (GLP) standards and negotiation of agreements | • Processes for negotiating agreements and managing intellectual property (IP) established  
• Centres with ethics committees | • Regional centres of excellence performing sustainable R&D within international standards  
• Accessible guidelines and publications |
| **Strategic objective 5:** facilitate interface with existing initiatives, PPPs, biotechnology and pharmaceutical companies and regional networks (ANDIs) to promote broader north–south and south–south collaborations to enhance technology utilization and transfer | • Two centres of excellence or biotechnology platforms supported and accredited | • Collaboration or partnerships to support and enhance technology utilization and transfer, including establishment of biotechnology and centres of excellence (2013) | • Sustainable centres of excellence contributing to local innovation |
2. Key stakeholders, roles and responsibilities

The implementation of BL4 is supported by the input of several stakeholders.

1. Researchers from academia and industry, including those identified through calls for grant applications.

2. National governments, regional and subregional bodies, policy-makers, ministries of health, science and technology, trade and industries.

3. Resource contributors and donors, including developed and developing countries, foundations, regional development banks and international organizations.


5. Research institutions, including academia, pharmaceutical and animal health companies and PPPs.

This range of stakeholders is also reflected in the composition of the ANDI task force (Annex 5.2).
3. Implementation plan 2009–2013 and progress

3.1 Scope of activities

This business line focuses on promoting and supporting innovation in Africa, Asia, the Middle East and South America. It helps to map the existing R&D landscape and identify needed capacity to support innovation. This mapping will facilitate the development of regional networks to support health product R&D in the areas of research, discovery and development (translational research) of drugs, diagnostics and other health interventions. This broad scope is necessary to create a sustainable platform or mechanism for R&D innovation in developing countries. The focus is not on one or two diseases or projects but on the needs or priorities of a particular region. This is consistent with this business line’s objective of focusing on promoting innovation for product development in developing countries. The goal is for the regional innovations networks to further stimulate south–south collaboration (Fig. 4), as well as north–south collaboration. The two-phased strategy described in Fig. 1 is ideal for the implementation of these objectives. The activities and end-products up until 2013 are summarized in subparagraph 1.4 and Table 1. Specific activities, plans and deliverables for the 2010–2011 biennium are presented in Annex 5.3.

Fig. 4. Regional innovation networks
3.2 Plan, progress and key milestones

Strategic objective 1: define gaps and opportunities for innovative R&D in the south through regional mapping of the R&D landscape.

The African R&D landscape, published in 2008, was updated in 2009 as part of the development of the SBP for ANDI (SBP, see http://meeting.tropika.net/andi2009/files/2009/10/sbp-final_web.pdf). This analysis involved visits to different countries (Nigeria, Egypt, South Africa, Kenya, Burkina Faso), interviews with over 170 scientists, policy-makers and stakeholders in Africa and over 60 stakeholders outside of Africa, and reviews of over 30 000 peer-reviewed articles published from 2004 to 2008, over 150 patents, and more than 120 manufacturing facilities in Africa. As a result of this mapping, several challenges and opportunities for ANDI were identified and used as the basis for the development of the SBP.

The identified challenges include:

- **Research gap** – most diseases that are predominant in Africa still have empty product pipelines, with few or no ongoing clinical trials (e.g. schistosomiasis, trypanosomiasis).
- **Lack of intra-African collaboration** – less than 5% of biomedical articles published from 2004 to 2008 involve two or more African countries, with most of the collaborations biased externally towards the developed countries. This fact is illustrated in Fig. 5 for HIV/AIDS research, but the same is true for malaria and other infectious diseases as well as epidemiology research (see strategic and business plan for ANDI for more details).
- **Significant investment gap** – Africa invests below 50% of the world median on R&D, with the gap on drugs/diagnostics innovation estimated at US$ 1.0–2.4 billion/year (Fig. 6).

![Biomedical collaborations are biased towards the developed countries, e.g. HIV/AIDS research](image_url)
Strategic objective 2: facilitate creation of regional innovation networks in the south dedicated to the discovery and development of drugs, diagnostics and other health products and technologies in DECs.

Key achievements include the successful implementation of the recommendations from the 1st ANDI stakeholder’s meeting in Abuja, which include:

- Establishment of a task force to develop the SBP for ANDI, covering the scope of work, organizational and governance structure, implementation and human resources plan and budget. The composition, terms of reference and final report of the task force presented at the 2nd ANDI stakeholder’s meeting can be found at (http://meeting.tropika.net/andi2009/files/2009/10/taskforce_report_web.pdf).
- The successful launch and adoption of the ANDI business plan at the 2nd stakeholder’s meeting in South Africa (refer to resolution at http://meeting.tropika.net/andi2009/2009/10/06/resolution-of-the-2nd-stakeholders-meeting-of-the-african-network-for-drugs-and-diagnostics-innovation-andi/).

This significant analysis was presented at the 2nd ANDI stakeholder’s meeting in Cape Town in October 2009. ANDI can help leverage these existing opportunities to overcome identified challenges.

Other achievements in 2009 include:

- Mapping of the China R&D landscape which will feed into a broader Asian mapping exercise.
- Initiation of mapping activities for India and the 10 member countries of ASEAN.

• The identified opportunities include:
  - Several competency centres performing competitive R&D across the product value chain but not currently collaborating with each other (Fig. 7).
  - Several clinical trial centres with the capacity to conduct good clinical practice (GCP) clinical studies.
  - Several African institutions with biomedical patent activity (Fig. 8).
  - Many downstream commercial partners (about 130 companies) that can support product commercialization, although the GMP (good manufacturing practice) status of these companies is not clear. The GMP status can easily be upgraded if they are found lacking.

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- Mapping of the China R&D landscape which will feed into a broader Asian mapping exercise.
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Key achievements include the successful implementation of the recommendations from the 1st ANDI stakeholder’s meeting in Abuja, which include:

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- The successful launch and adoption of the ANDI business plan at the 2nd stakeholder’s meeting in South Africa (refer to resolution at http://meeting.tropika.net/andi2009/2009/10/06/resolution-of-the-2nd-stakeholders-meeting-of-the-african-network-for-drugs-and-diagnostics-innovation-andi/).

This significant analysis was presented at the 2nd ANDI stakeholder’s meeting in Cape Town in October 2009. ANDI can help leverage these existing opportunities to overcome identified challenges.

Other achievements in 2009 include:

- Mapping of the China R&D landscape which will feed into a broader Asian mapping exercise.
- Initiation of mapping activities for India and the 10 member countries of ASEAN.
- Cities with 30 or more articles published in the 2004-08 period
- Total of 90 cities in 27 countries
- 16,647 biomedical articles led by African authors included in analysis

Fig. 7. Mapping of African research output reveals that several competency centres exist
(see the ANDI strategic and business plan http://meeting.tropika.net/andi2009/files/2009/10/sbp-final_web.pdf)

Fig. 8. Some African centres show patent activity in the biomedical areas
A top level summary of the deliberations of the ANDI task force is as follows:

- The 1st task force meeting was held in Geneva in February 2009. The task force:
  - reviewed and agreed to its terms of reference (TOR);
  - defined timelines for work and delivery of the SBP for ANDI;
  - discussed various strategic options and identified potential areas of focus for ANDI;
  - initiated recruitment of consultant to help with SBP development.

- Follow-up teleconference in April 2009:
  - reviewed and short-listed consultants;
  - assembled the local organizing committee for the 2nd ANDI stakeholder’s meeting in October 2009.

- The 2nd task force meeting held at the African Development Bank, Tunis in May 2009:
  - selected consultant McKinsey & Co, met with the task force;
  - agreed the work plan, deliverables and method of work for consultant;
  - advanced discussion on scope of work, structure and governance of ANDI.

- Follow-up teleconference in July 2009:
  - reviewed draft SBP and discussed October meeting.

- The 3rd task force meeting held at the WHO country office in Burkina Faso in August 2009 prepared the:
  - final review and input on the SBP;
  - plan for launch of the SBP in Cape Town in October 2009.

- Follow-up teleconference – August 2009
  - finalized and adopted the SBP;
  - reviewed updates from the local organizing committee for the 2nd stakeholder’s meeting.

Other achievements include:

- ANDI mentioned in the report of WHO to the 124th Session of the Executive Board (EB124/16) held in January 2009.
- ANDI recognized at the 62nd World Health Assembly in resolution WHA62.16 (May 2009) as an important initiative under the GSPOA.

- The strong engagement of both the ministries of health and science and technology in the development of the regional networks. African ministers of science and technology and health who attended the October 2009 ANDI meeting expressed strong support and endorsement for ANDI. They agreed to bring ANDI to the attention and recognition of their respective governments.

- Discussion and planning for the initiation of networks of product innovation in the Asian region (China, India and ASEAN):
  - Launching of the China NDI and initial mapping result in a meeting in Shanghai attended by over 100 participants, including representatives from the ministries of health and science and technology.
  - The brainstorming meeting in Manila of the ASEAN NDI.

Strategic objective 3: to support the 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.

- This activity will be initiated in 2010.

Strategic objective 4: to coordinate the development of standard operating procedures to support the discovery and development in DECs.

- These objectives are recorded in the SBP for ANDI, but progress towards implementation will be reported in 2010/2011.

Strategic objective 5: to facilitate interface with existing north–south/south–south initiatives, PPPs, biotechnology and pharmaceutical companies 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 the interfacing activity that can be leveraged to support innovation in developing countries. The plan is for BL4 to intensify the interface with other business lines and external initiatives, including PPPs, government and other international initiatives, as well as existing regional initiatives.
### 3.3 Financial analysis

**TABLE 2. FINANCIAL IMPLEMENTATION 2008–2009**

<table>
<thead>
<tr>
<th>Title</th>
<th>JCB approved budget 2008–2009 (US$ 121 million)</th>
<th>Funds available (B)</th>
<th>Expenditures 2008–2009 (C)</th>
<th>Implementation as a % of funds available</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL4 Innovation in DECs</td>
<td>1 310 000</td>
<td>725 000</td>
<td>644 011</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>Mapping (database development)</td>
<td>465 000</td>
<td></td>
<td>70 373</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding for full projects</td>
<td>200 000</td>
<td></td>
<td>157 560</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exploratory projects</td>
<td>190 000</td>
<td></td>
<td>2 239</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support centres &amp; networks</td>
<td>120 000</td>
<td></td>
<td>37 152</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coordination</td>
<td>335 000</td>
<td></td>
<td>371 190</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRIMALDDI (The Coordination, Rationalisation and Integration of Antimalarial Drug Discovery and Development Initiatives)</td>
<td>0</td>
<td></td>
<td>5 497</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.4 Implications of progress/delays and global context changes on 2009–2013 plans

Implication of changes in global context
As shown in Fig. 9a, 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 with industry and academia. The picture is even worse for diagnostics, where very few discovery activities are ongoing for several neglected diseases (Fig. 9b). In addition to recent efforts in promoting translational innovation, for example through the Gates Grand Challenges and other funding institutions, a major change in the past 2 years is the intergovernmental discussion and support for innovation that has resulted in the approval of the GSPOA through WHA resolutions WHA61.21 and 62.16. This emphasis and the support 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. The concept of regional innovation networks exemplified by ANDI is a practical approach initiated by TDR in implementing R&D activities in developing countries and it is hoped that it will attract more attention from the international community in the coming months and years. As highlighted above, the May 2009 WHA62.16 resolution specifically highlights ANDI as an important initiative aimed at implementing the GSPOA. This recognition is also reflected in the SBP of ANDI as well as the mini-business plan covering TDR activities toward the implementation of the GSPOA on public health, innovation and intellectual property.

![Fig. 9. Translational innovation gap. a. Drug discovery and, b, diagnostics discovery for infectious tropical diseases](image-url)
3.5 Activities for 2010 and budget for 2010–2011

Some activities for 2010 are highlighted below:
- Initiate implementation of the activities outlined in the ANDI SBP (Fig. 3), including management of:
  - establishment of the ANDI board and STAC;
  - initiation of call for grant applications;
  - the 3rd ANDI stakeholder’s meeting in October 2010 in Kenya;
  - identification of African host institution and subregional hubs for ANDI 2010/2011;
  - transition of ANDI from TDR to African host institution in 2010/2011.
- Implement consultation meetings for the Asian and Middle East NDI:
  - China NDI – report of China consultation and mapping made available (Q4 2010);
  - India NDI – initial meeting and mapping implemented (2010);
  - ASEAN NDI – report of consultation and mapping result made available (2010);
  - Middle East NDI – informal consultation meeting held (2010).
- Implement consultation meetings for the Americas (South American) Network for Drugs and Diagnostics Innovation:
  - informal consultations and initiation of R&D landscape mapping (2010).

### TABLE 3. APPROVED BUDGET IN 2010–2011

<table>
<thead>
<tr>
<th>Title</th>
<th>JCB approved budget 2010–2011 US$ 121 m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mapping (database development)</td>
<td>150 000</td>
</tr>
<tr>
<td>Funding for full projects</td>
<td>0</td>
</tr>
<tr>
<td>Exploratory projects</td>
<td>300 000</td>
</tr>
<tr>
<td>Support centres and networks</td>
<td>150 000</td>
</tr>
<tr>
<td>Coordination</td>
<td>380 000</td>
</tr>
<tr>
<td><strong>Total – BL4 - Innovation for product development in developing countries</strong></td>
<td><strong>980 000</strong></td>
</tr>
</tbody>
</table>
4. Leverage, and contributions to stewardship and empowerment

4.1 Leverage

Through the ANDI initiative, several African institutions are already beginning to exchange information and R&D ideas. For example, the Kenya Medical Research Institute, the National Institute of Pharmaceutical Research and Development in Nigeria, and screening centres in Africa such as the University of Buea in Cameroon and the Theodor Bilharz Research Institute in Egypt are now exploring collaborative projects that could further strengthen intra-African activities as well as broaden south–south activities. In addition, BL4 is also leveraging BL3 activities to support innovation in developing countries through: a) supported BL3 hit-to-lead projects at the University of Cape Town and the African Institute of Biomedical Science and Technology (AiBST) in Zimbabwe; b) TDR lead identification project for Chagas disease at the University of São Paulo which has helped to establish a strong screening and medicinal chemistry programme; c) a high throughput screening activity at the National Centre for Drug Screening in Shanghai, which is supporting the training of African scientists. All these represent significant empowerment activities in developing countries. ANDI was highlighted at the 2009 WHA through resolution WHA62.16 as an important initiative under the GSPOA. This has brought additional technical and political visibility and support for ANDI. For example, several African and foreign governments and institutions are now aware of ANDI and supportive of the ANDI concept. The European Commission has provided funding to support the establishment of the regional innovation networks for Africa (ANDI), Asia and South America. The African Development Bank has supported the activities of the ANDI task force and discussions are ongoing about possible funding and legal hosting arrangements for ANDI, including the African Innovation Fund. The Department of Science and Technology of South Africa and the European Commission provided financial support for the 2nd ANDI stakeholder’s meeting in Cape Town. McKinsey and Company supported ANDI through the development of its SBP at significantly reduced costs compared to the standard market rate.

The support of leading experts who served on the ANDI task force at little or no cost is a significant leverage.
4.2 Contributions to overall empowerment and stewardship objectives (DECs playing a pivotal role)

BL4 is at the heart of supporting and advocating a pivotal role of DECs in product R&D. The work is supporting significant stewardship and empowerment functions in developing countries. The leadership and ownership of ANDI by Africans is evident through their role in identifying the needs, priorities and scope of activities defined in the SBP for ANDI. These were achieved through the ANDI meeting in Abuja and Cape Town in 2008 and 2009 respectively, as well as through country visits and consultations by the ANDI task force in different African regions. The ANDI task force membership comprises a significant number of African experts, and the same is envisaged for other regional networks. Other examples of the empowerment function include the training of developing country researchers on innovation. The mapping of R&D landscape in Africa, Asia and South America by the scientists themselves is an important and necessary empowerment and stewardship function because it is resulting in the setting of local priorities based on local capability, gaps and opportunities. Meetings and invited lectures given as part of promoting innovation are listed in Annex 5.3.

4.3 Elements enhancing sustainability of BL4 outcome

The key elements to enhancing the sustainability of the BL4 outcome include the strong participation, ownership and leadership of developing countries in the activities of the business line. This fact is exemplified by the commitment and enthusiasm of African scientists and institutions, including those in the diaspora, policy-makers and the ANDI task force in all the activities leading to the establishment of ANDI.
5. Annexes

5.1 Full list of publications resulting from BL4 or related activities

ANDI task force report

ANDI strategic and business plan

ANDI outcome & resolution

(http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673609608382.pdf?id=aeaa5a245ca1fdd:-7469e6a2:1216a4c171f:-3b411243031051689, accessed 8 February 2010).

5.2 SAC responsibilities and membership

ANDI task force members and terms of reference

Following the recommendations at the inaugural meeting of the African Network for Drugs and Diagnostics Innovation (ANDI), attended by over 200 participants from 21 countries and held at Abuja (on 6–8 October 2008), a task force for ANDI was constituted.

MEMBERS of the ANDI task force
1. Dr Tom Mboya-Okeyo (Chair), Kenyan Ambassador to UN Geneva
2. Dr Alex Ochem (Secretary), ICGEB, South Africa
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, University of Nairobi, Kenya
7. Dr Tshinko Ilunga, Manager Health Division, Human Development Department, African Development Bank
8. Dr Peter Atadja, Novartis (representing Africans in diaspora)
9. Dr Kevin McCarthy, representative of the EU
10. Dr Robert Ridley, TDR Director
11. Dr Solomon Nwaka, Leader of Drug Discovery and Innovation Research (focal point for ANDI and task force activities)
### 5.3 Specific activities and deliverables for 2010–2011 biennium (and until 2013)

<table>
<thead>
<tr>
<th>2010–2011 activities</th>
<th>Through 2013</th>
</tr>
</thead>
<tbody>
<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 and capabilities</td>
<td><strong>- Four reports describing the R&amp;D landscape for Africa, Asia, South America and the Arab states (Middle East) made available</strong>&lt;br&gt;<strong>- A database of institutions, investigators and projects from various regions made available (2013)</strong></td>
</tr>
<tr>
<td>Implement consultation meetings for the Asian, Middle East and South American NDIs:&lt;br&gt;  • China NDI – report of China consultation and mapping made available (Q4 2010)&lt;br&gt;  • India NDI – initial meeting and mapping implemented (2010)&lt;br&gt;  • ASEAN NDI – report of consultation and mapping result made available (2010)&lt;br&gt;  • Middle East NDI – informal consultation meeting held (2010)&lt;br&gt;  • South American network – informal consultations and initiation of R&amp;D landscape mapping (2010)</td>
<td></td>
</tr>
<tr>
<td><strong>Strategic objective 2:</strong> facilitate the design, creation and implementation of regional innovation networks in the south dedicated to the discovery, development and delivery of drugs, diagnostics and other health products and technologies in DECs</td>
<td><strong>- Four regional networks for product R&amp;D in Africa, Asia, South America and the Arab states (Middle East) established</strong>&lt;br&gt;<strong>- Strategic and business plan for South American network and Middle East network (2012)</strong>&lt;br&gt;<strong>- Report of mapping of R&amp;D landscape for Asia (2012)</strong>&lt;br&gt;<strong>- Report of mapping of R&amp;D landscape for South America (2012)</strong>&lt;br&gt;<strong>- Website and database to support network collaboration and interaction</strong></td>
</tr>
<tr>
<td>ANDI transitioned to Africa:&lt;br&gt;  • Implement the ANDI activities outlined in Fig. 3, which include the following actions:&lt;br&gt;  • Establishment of ANDI board and launching it at 3rd stakeholder’s meeting in Nairobi (Q4 2010)&lt;br&gt;  • Identification of initial ANDI projects through call for application (Q4 2010)&lt;br&gt;  • Manage the identification of African host institution and subregional hubs for ANDI 2010/2011&lt;br&gt;  • Manage the transition of ANDI from TDR to African host institution in 2010/2011&lt;br&gt;  • Asian network:&lt;br&gt;  • China NDI – report of China consultation and mapping made available (Q4 2010)&lt;br&gt;  • India NDI – mapping initiated (Q1 2010)&lt;br&gt;  • ASEAN NDI – report of consultation and mapping made available (Q4 2010)&lt;br&gt;  • Broad Asian meeting held with agreement on structure of the Asian network (2011)&lt;br&gt;  • SBP developed (2011)&lt;br&gt;  • Arab States Network:&lt;br&gt;  • Informal consultations and initiation of R&amp;D landscape mapping (2010)&lt;br&gt;  • Americas Network:&lt;br&gt;  • Informal consultations and initiation of R&amp;D landscape mapping (2010)</td>
<td></td>
</tr>
</tbody>
</table>
### Strategic objective 3:
**Support competitive discovery and development projects for novel diagnostic tests, drugs and other products for tropical diseases in Decs through targeted calls for application that will eventually feed into regional networks**

- Initiate calls for application and project review
- Review, select and fund projects

<table>
<thead>
<tr>
<th>2010–2011 activities</th>
<th>Through 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Portfolio of about five discovery and development projects in developing countries funded and managed, including transfer of promising projects to the regional network</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Four projects transferred to regional networks (2013)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>One health product transitioned from discovery to development (2013)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>One new diagnostic kit developed (2013)</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Strategic objective 4:
**Coordinate the development of standard operating procedures (SOPs) to support product R&D in Decs**

- Two centres implementing SOPs for drugs and diagnostics R&D in developing countries

<table>
<thead>
<tr>
<th>2010–2011 activities</th>
<th>Through 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Support the development of SOPs and courses for product R&amp;D, including legal and IP frameworks to support the discovery and development of pharmaceuticals in Decs</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Five centres implementing SOPs for drugs and diagnostics R&amp;D in Africa, Asia, South America and the Arab states (Middle East) (2013)</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Strategic objective 5:
**Facilitate interface with existing initiatives, PPPs, biotechnology and pharmaceutical companies and regional networks such as ANDI to promote broader south–south and north–south collaboration for technology utilization and transfer**

- One centre of excellence or biotechnology platforms supported and accredited

<table>
<thead>
<tr>
<th>2010–2011 activities</th>
<th>Through 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Two centres of excellence or biotechnology platforms supported and accredited</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Collaboration between regional networks (NDIs) and existing north–south, south–south partnerships to support and enhance technology utilization and transfer, including establishment of biotechnology and centres of excellence (2013)</strong></td>
<td></td>
</tr>
</tbody>
</table>
The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration established in 1975. Its focus is research into neglected diseases of the poor, with the goal of improving existing approaches and developing new ways to prevent, diagnose, treat and control these diseases. TDR is sponsored by the following organizations: