

PROPOSAL TEMPLATE

Proposal Name: *Integrated regional and global coordination and financing mechanism of R&D for diseases that disproportionately affect developing countries - the ANDI model*

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Description of the proposal:

A coordinating and financing model for R&D is proposed that is based on the formal establishment of regional and sub-regional networks under representative governance. These can address finance and sustain R&D innovation for diseases that disproportionately affect developing countries. By linking these networks into a global 'Network of Networks' model, supported by a small central secretariat, a coherent approach to address the objectives of the GSPOA can be developed.

This approach, with funds, staff and autonomy based within the regions, provides a decentralized approach to decision making that addresses local needs. It also offers multiple options for financing, as the networks can access global, regional, sub-regional and nationally available resources. Many of these opportunities would not be available for an international initiative. The networks can also negotiate in kind resources e.g. through national research councils, in a way that would not be possible for a centralized global organization.

This approach is complimentary to, and not in competition with, existing disease-focused approaches such as public private or product development partnerships (PPPs or PDPs). It also allows for the development of local public private partnership projects.

The proposed mechanism has a very strong capacity building element, through enhanced intra-regional collaboration, building on regional centres of excellence.

The model is exemplified by the recent establishment of ANDI - the African Network for Drugs and Diagnostics Innovation. With a certain level of central coordination and support, similar networks are under discussion within ASEAN -Association of Southeast Asian Nations and the Americas through PAHO. National networks are also being established in China and India.

The governance and operational structures will vary from region to region, but several core elements are envisaged: (a) representation from health and science and technology ministries; (b) engagement of non-governmental sectors, both private sector and civil society; (c) independent scientific and technical advice, with independent peer review of funded research; (d) thorough but light bureaucracy.

This proposal further outlines the value of this approach and addresses the CEWG criteria:

- (i) public health: enhanced local R&D capacity; linkage of R&D to local manufacture, stimulating potential for sustainable production and access to health products;
- (ii) technical feasibility: ANDI, has already formally been established with core processes in place; others networks are under discussion
- (iii) financial feasibility: the potential to access regional and other local funding as well as international funding.
- (iv) cross cutting issues: the regional focus leads to a holistic, rather than a disease, or issue-based, approach. This, with representative governance means that it is easier to address issues such as IP, capacity building, equitable access, partnership.
- (v) key steps: funds and increased coordination support are the main elements required to make this model a reality. Recommendation of this approach by the CEWG would be an important milestone
- (vi) evidence base: an increasing body of literature stresses the value of regional innovation; of public private partnerships; of networks for pharmaceutical

innovation. There are peer - reviewed literature reporting on the progress of, and support for, this regional innovation network model.

Please see references 1, 2, 3, 4, 5, 6 - below.

Potential public health impact¹ of the proposal:

The network approach described here will lead to the development of more regionally owned R&D - led innovation as well as more regionally led manufacturing and production that will feed into sustainable regional public health use. It will ensure coherence and alignment of the various activities to the specific needs of developing countries. Most importantly, it will support sustainable capacity and infrastructural development as well as equitable access and delivery of health interventions in developing countries in the medium to long term. In addition, to contributing to the goals of the GSPOA, this approach will facilitate the achievement of MDGs, the Paris Declaration on Aid Effectiveness and other international and regional declarations (ref 1, 7, 8, 9, 10, 11).

The outputs that might be developed through this approach is best exemplified by the work of ANDI, whose specific objectives and deliverables include: i) developing a portfolio of high quality, pharmaceutical R&D projects that will result in new drugs, diagnostics, vaccines, medical devices and technologies to prevent and control diseases that disproportionately affect the African continent, and ensuring that these products are manufactured and locally accessed; ii) supporting a network of research centres of excellence that will share expertise, knowledge and contribute to capacity building across Africa; iv) brokering relationships with key stakeholders and promoting partnerships between the public and private sectors; and v) facilitating intra-African and broader South-South collaboration as well as North-South collaboration.

¹ Principally CEWG criterion 1 but others may be relevant e.g. Equity/distributive effect including on availability and affordability of products and impact on access and delivery.

Steady progress has been made in the past 3 years in trying to achieve these objectives and deliverables:

i) a call for proposals that was launched in the 4Q 2010 resulted in 207 applications from all regions in Africa. The initial review of the proposals has been undertaken by the ANDI Scientific and Technical Advisory committee (STAC) with the short-listing of about 50 projects, which have been requested to submit detailed proposals. A final review and selection of the top 5 to 10 projects for possible funding will be undertaken later this year. This is a significant step towards developing the ANDI portfolio of quality pharmaceutical R&D projects that may result in new drugs, diagnostics, vaccines, medical devices and technologies to prevent and control diseases that disproportionately affect the African continent.

ii) The first ever call for proposals to identify and accredit Centres of Excellence (CoE) across Africa based on a set of criteria and rigorous review process, was initiated last year. The review of the over 117 applications received was finalized at the 1st meeting of the ANDI STAC meeting in Addis Ababa in May 2011. A formal announcement and recognition of the Centres will take place at the 4th ANDI Stakeholders Meeting scheduled for 24-27 October 2011 in Addis Ababa, Ethiopia. This announcement is another mechanism to recognize and reward innovation. These centres will be networked and be used to support ANDI portfolio of projects and capacity building including training of young African scientists and researchers. It should be mentioned that these centres include both public, private and non governmental institutions in Africa and their area of work cover the entire R&D value chain including manufacturing and commercialization of products. This is major innovation that could contribute to achievement of health impact in the medium to long term including MDGs.

In addition, the following have also been achieved by ANDI:

- Successful implementation of 3 major pan-African stakeholders' meetings, the last was held in Nairobi, Kenya and attended by over 500 participants from over 40 countries from across the globe, including representatives from 30 African countries covering all the regions (ref 12, 13, 14).
- Implementation of memorandum of understanding (MoU), between WHO and UNECA to enable UNECA to host ANDI as a partnership.

- The establishment of an innovative governance structure, including a ministerial level Board and an independent Scientific and Technical Advisory Committee (STAC).
- Development of knowledge management database

The overview of ANDI value proposition is summarized in Figure1

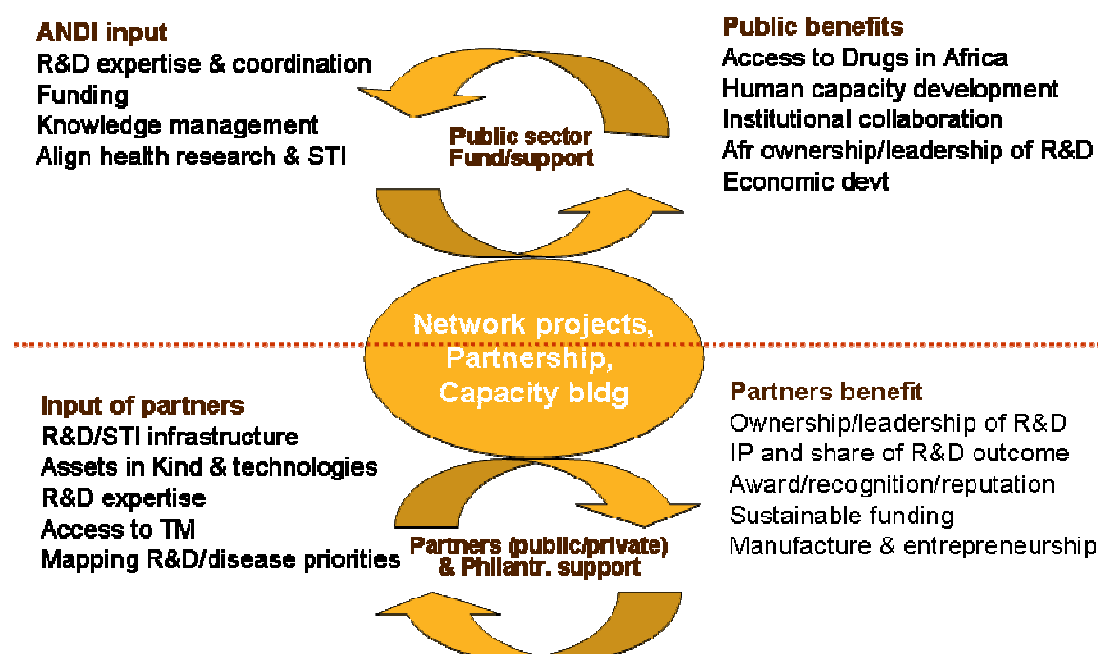


Figure 1: ANDI impact - value proposition. Highlights the potential impact of the work of ANDI in collaboration with all stakeholders

Technical feasibility² of the proposal:

The potential to develop regional networks has already been demonstrated by ANDI. The establishment of a high level Board, co-chaired by the Minister of Health for Kenya and the Minister of Science and Technology for South Africa, further exemplifies its potential significance for the region. Other networks, as mentioned above, are already in development.

ANDI was established as an initiative under the auspices of UNECA. The technical feasibility was supported by a variety of R&D landscape analysis, broad consultation in Africa and overseas which helped to identify local needs priorities, as well as

opportunities and gaps (ref 2, 3, 4, 15). All these informed the establishment of ANDI and the development of its strategic business plan (ref 2, 3).

The strategic business plan's development involved multiple consultative discussions, analyses and over 170 stakeholder interviews.

An analysis of scientific publications from 2004 to 2008 illustrates the partnering activities of African institutions and demonstrates the potential value of an African-based network. For HIV biomedical research, the top 20 institutions working in or with Africa were identified and the collaborative links of the African institutions mapped. The results, shown in figure 2, demonstrate that the vast majority of African institutional collaboration is with external institutions in the USA and Europe. This same picture is seen for other diseases disproportionately affecting Africa as well as biomedical patent landscape (ref 2, 3). This extra-continental collaboration in itself is not a bad thing, but there is an obvious need to further strengthen intra-African collaboration. By complementing existing activities with a strengthened intra-African collaboration, African innovation capacity and increased African ownership and control of research can be better developed.

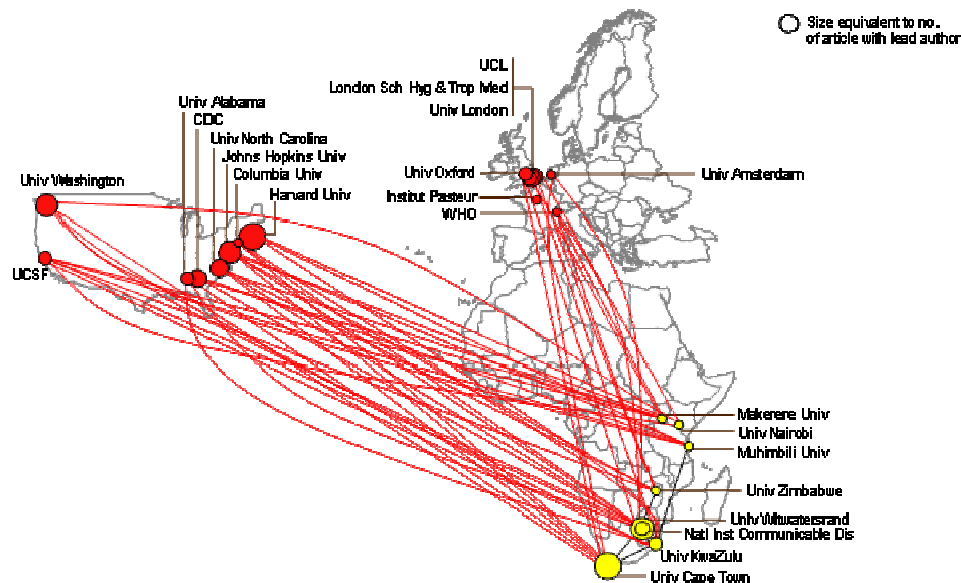


Figure 2: Top collaborative linkages between African institutions in the fields of HIV/AIDS demonstrate that over 95% of collaborations are external to Africa

Figure 3 demonstrates that basic innovation capabilities exist, but also highlights the uneven geographic nature of those capabilities. By generating sub-regional hubs for a pan-African network, and by linking this to a governance structure that has strong

sub-regional representation, it is anticipated that ANDI will help leverage technology transfer and capacity building from the stronger sub-regional institutions to weaker sub-regional institutions. One of ANDI's key objectives is to create networks and synergies between African institutions that strengthen South-South and North-South collaborations

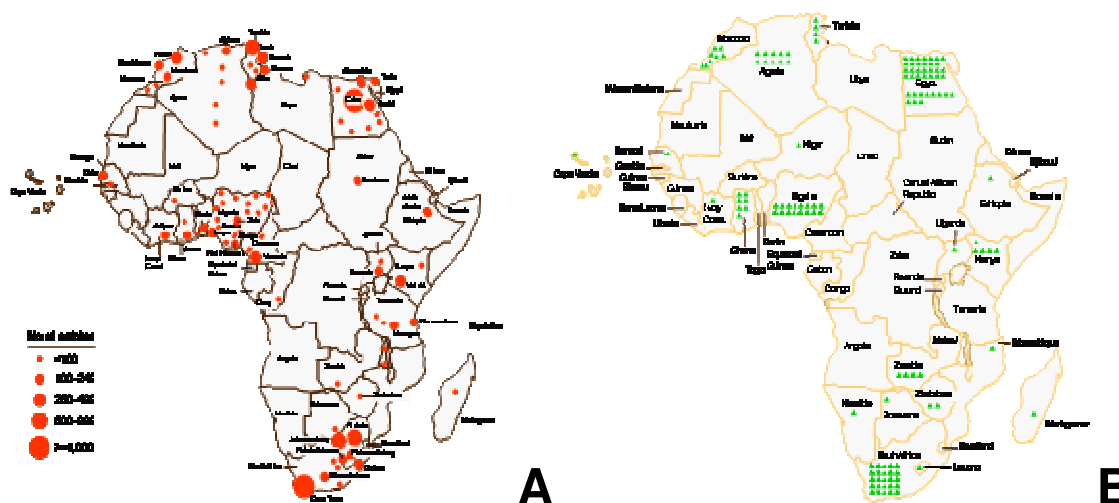


Figure 3: Top centres in Africa for: A, biomedical research publications, and B, manufacturing capacity

It is expected that a functional organization located in Africa, owned, managed and governed by African institutions, implementing product R&D and ensuring sustainable access to new drugs and diagnostics innovations, will help fill a number of gaps: first, a lack of investment in product R&D within Africa; second, a lack of collaboration among African scientists and between the African public and private sector; and third, a lack of awareness of the link between research and economic development.

Preliminary data from Asia and South America show that significant capability exist for innovation.

Financial feasibility³ of the proposal:

A recent report of G-Finder (ref 22) demonstrated that India, Brazil and South Africa

are now among the top 12 contributors globally to the financing of R&D for neglected diseases. This illustrates that there is potential for substantive financing for innovation within regions affected by diseases that disproportionately affect developing countries. Middle income countries and emerging economies can assist driving forward regional approaches. Lower income countries are also committing more to financing innovation and science and technology. For example, Tanzania has committed to spend 1% of its GDP on science, technology and innovation. Such efforts can also be reinforced by the regional development banks and the local private sector. The financing needs for ANDI have been developed in detail and are illustrated below. An estimated \$30M per year would provide for the development of a solid regional portfolio of R&D projects (ref 2, Figure 4).

Similar business and strategic plans are under development for other networks. They give an idea of the types of resources that could generate a significant impact.

The ANDI business plan outlines the creation and management of an 'Innovation Fund' to finance drugs and diagnostics research. One idea is to create an endowment fund in Africa that can complement other, more classical donations to generate a sustainable annual income of up to US\$ 30 million to ANDI operation and projects. Discussions are under way with the African Development Bank to host this fund but in the time being an ANDI Trust has been established at UNECA. This plan has been developed by a Task Force that includes partners from several national African institutions and the African Diaspora, in collaboration with WHO through TDR, the AFRO and EMRO, AfDB, UNECA, and the EU.

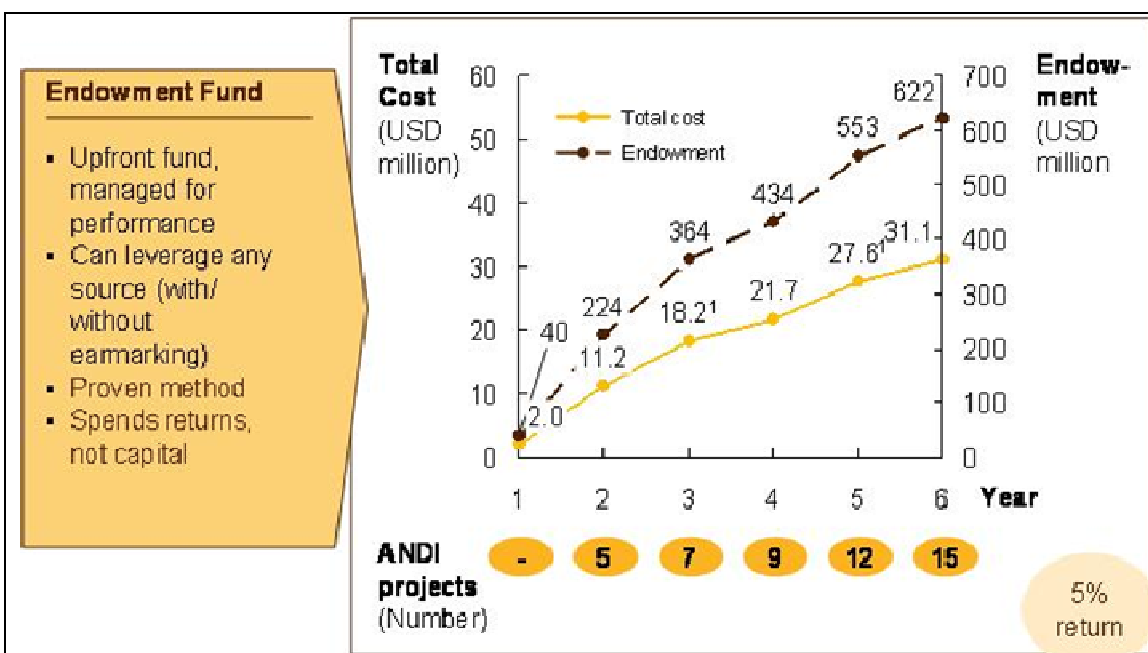


Figure 4: Funding requirements ANDI work on R&D known. The ANDI Trust Fund has been established with the goal to establish an endowment fund for the medium/long term for sustainability

How the proposal addresses cross-cutting issues¹:

Various cross-cutting issues identified in CEWG criteria are addressed below. Again, the example of ANDI 's response is given.

CEWG Criteria 7: IP management - as highlighted in the strategic business plan (ref 2), ANDI's work covers capacity building and training for IP management in collaboration with other agencies. This is a major area of need identified during the mapping of the R&D landscape in Africa. In addition ANDI is working to finalize its IP strategy and policy in relation to concrete projects and access to products in Africa. Similar considerations would need to be addressed by other networks, taking into account their special regional issues.

CEWG criteria 8: Potential for de-linking R&D cost and price of products - some of the existing push and pull mechanisms are aimed at achieving this objective. However, at the moment these mechanisms are not integrated. For example, the PDP's are doing an excellent work in R&D and some products are now available on the market. However, it is not always clear how the products that result from these efforts will be made available to developing countries in an affordable and sustainable way. In particular, the link to local and sustained manufacture and

delivery in developing countries is limited.

Regional networks offer a strong potential to link R&D to local manufacture and production. This model, coupled with other sources of financing, provides opportunities for de-linking R&D costs and cost of final product. For example, ANDI is developing a financing mechanism that can potentially de-link the 2 process by attempting to develop a strategy to manage the interface between R&D and access (Figure 5). This involves both a financing, review and monitoring & evaluation mechanisms for supporting R&D such that the cost of R&D and associated attrition is de-linked or not impacting the cost of the final product. Under this scenario, the cost of the final product might only be impacted by the cost of targeted late state studies, registration, manufacture and distribution. This is because, the funding model for this downstream activities might require a mix of venture, social venture or equity funds as well as public, private and philanthropic funds. It is critical to have this combination of approaches to ensure that local innovation is not stalled and to encourage local entrepreneurship and involvement of SMEs in this effort. This will contribute to sustainability in the long term.

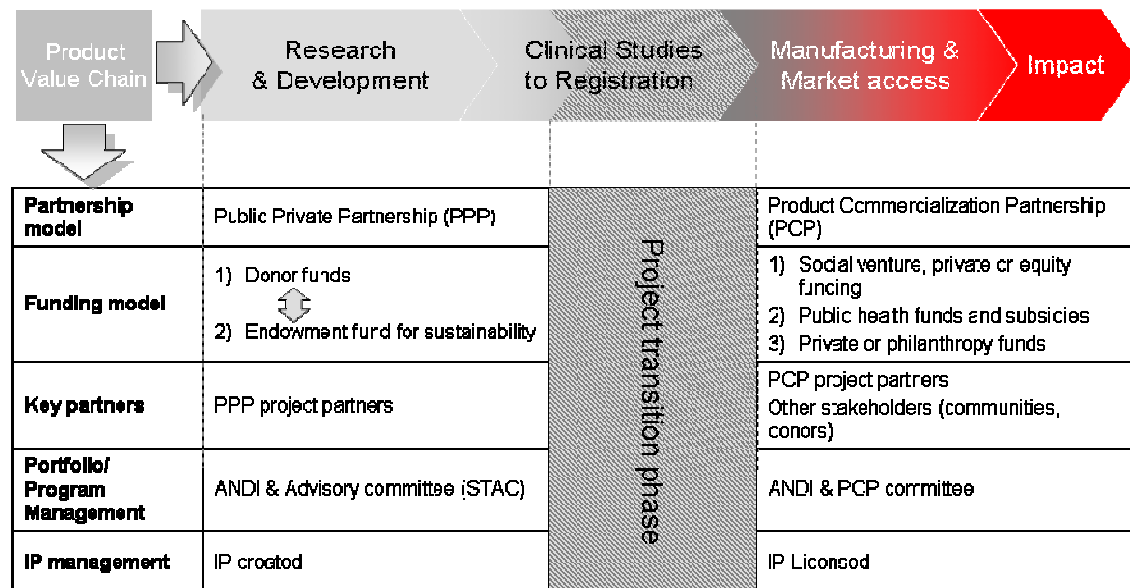


Figure 5: Proposed ANDI financing and product transition scheme (draft). The scheme tries to address a variety of transition and access issues.

CEWG Criteria 9: Equity/distribution effects including on availability and affordability

of products and impact on access and delivery - the overall goal of ANDI is to create sustainable and long term mechanism for enhanced access to medicines and well being in Africa. This will entail developing local capacity and supporting African countries to take leadership and participate in the R&D and delivery of the products they need. This goes to the core of promoting equity in research and access to medicines at affordable costs. Linking the health sector, the science, technology and innovation sector, and the private sector through ANDI's governance structure allows for a dialogue on these issues.

CEWG Criteria 10: Accountability/participation in governance and decision making - ANDI has established an inclusive and innovative governance and operational structure (Figure 6), which is composed of a representative Board, a Scientific and Technical Advisory Committee ("STAC"), and an ANDI office and Host Agency. As the host agency is the United Nations Economic commission for Africa, this provides another level of governance oversight. The governance structure of other networks will need to take into account regional needs and variations.

1. The Board oversees the operational direction of the programme. It reviews and advises on, and approve the proposed plans of action, budget and financial statements prepared by the ANDI Secretariat through the official processes of the Executing Agency. The Board held its first meeting in January 2011 in Addis Ababa, Ethiopia. The involvement of ministries of health and science and technology as well as individuals from other works of life introduces a new innovation in health R&D governance. In addition, the hosting of ANDI at UNECA and representation of both UNECA and AfDB on the ANDI Board, brings the economic development angle of the work of ANDI to the fore. WHO brings the global health and normative perspectives to the work of ANDI
2. ANDI Secretariat refers to the central office of ANDI, its sub-regional hubs, a lean staff comprised of individuals employed under UNECA staff rules, who are responsible for the implementation of all ANDI activities under the management and leadership of the a Director.
3. STAC provides independent scientific and technical advice to the Board and the ANDI Secretariat in accordance with its terms of reference.

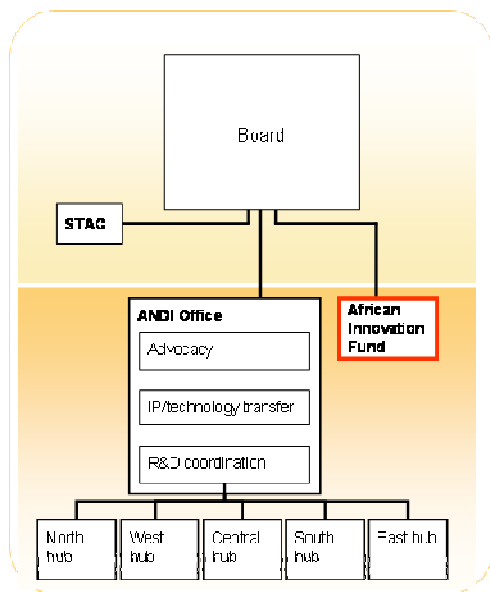


Figure 6: ANDI governance and organizational structure.

CEWG Criteria 11: Impact on capacity building in, and transfer of technology to, developing countries - this aspect has been covered earlier but goes to the heart of the ANDI approach. The ANDI Centres of excellence, projects, South-South and North-South partnerships will be clear instruments for capacity building and technology transfer.

CEWG Criteria 12: Potential synergy with other mechanism/potential for combining with others - the regional network model exemplified by ANDI is premised on partnerships, collaboration and synergy with others. It can be scaled up or down as required. As a result it can combine and link activities with others. Once other networks in Asia and America are established, they can virtually connect and collaborate with ANDI and each other through a central facilitation mechanism without undermining the independence of each (Figure 7).

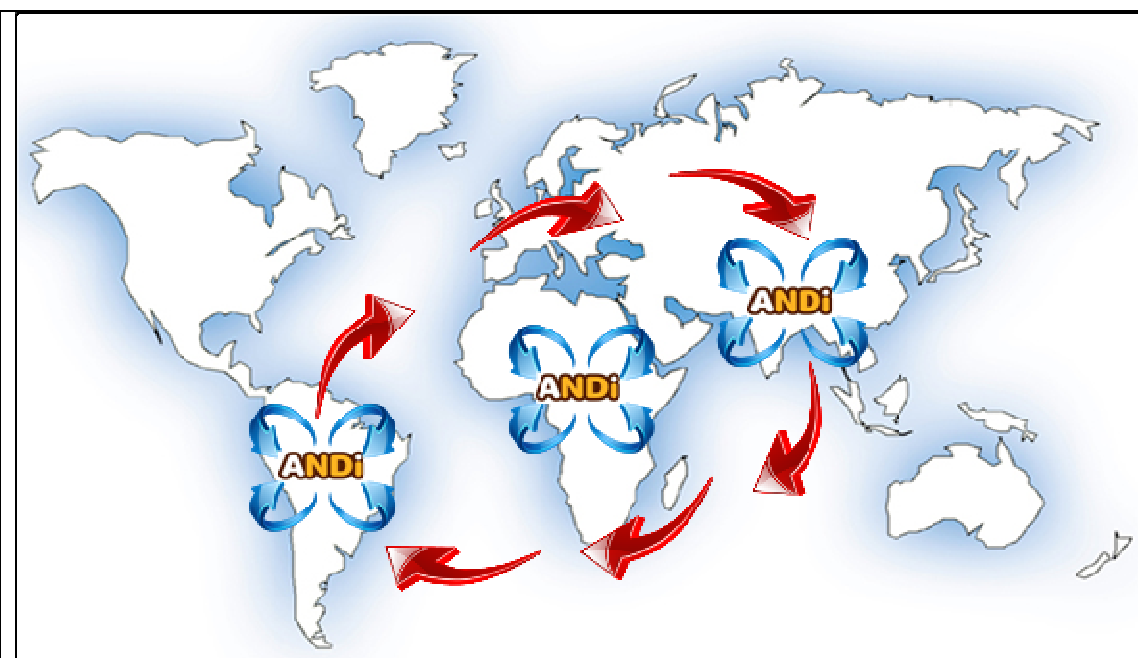


Figure 7: Leveraging the regional innovation network concept to support broad South-South collaboration as well as North South collaborations.

Key steps necessary to begin implementation and key issues to be resolved for implementation to begin:

ANDI was presented at the 1st CEWG meeting, and it was clear from the presentation that many of the issues raised in other presentations including capacity building and involvement of developing countries, IP management, de-linking R&D from cost of products, access to products could be addressed through the ANDI model.

The major challenge for ANDI, as presented to the CEWG is funding to support its operation. Funds are in place for its initiation and a small secretariat is in place, but more funds are now required to fully finance its operations, especially R&D. These can be provided direct to ANDI through UNECA. For the other networks for Asia and America - resources are needed to enable the development and establishment of the networks and to potentially extend their stakeholder base.

The model further requires that funds are secured to provide central support to the networks through a small and lean secretariat that can interface with the regional networks and other initiatives. This lean central office can be the mechanism for

information sharing, provision of advice and technical support.,

Such a model, linked to a central secretariat is also compatible with a Global Health R&D fund. The regional networks would each establish their own independent funds, but a global health R&D fund, able to bring in substantive international funds, could both promote R&D on global imperatives and provide an additional level of funding for the regional networks

Evidence base for the proposal including literature references and other relevant information:

In addition to the GSPOA, other intergovernmental actions have highlighted the capacity for innovation as a basis for human and economic development, including in the field of pharmaceuticals and health. In the case of Africa in particular, the development of ANDI was strengthened by: (i) Algiers declaration on research for health 2008 (ref 9), and the framework for its implementation (2009); ii) the AMCOST Cairo declaration in 2006 to 'promote research and development (R&D) and develop innovation strategies for wealth creation and economic development (ref 11); (iii) decision 55 taken at the Abuja summit of 2005, the mandating of the AU commission to develop a pharmaceutical manufacturing plan for Africa (ref 10).

From the public health imperative, direct evidence for the network and partnership model including the work of PDPs is well documented through work at TDR and PDPs (ref 5, 18, 19,20). However, it should be noted that the regional network model is an approach that goes beyond PDPs. ANDI was recognized at the World Health Assembly resolution on GSPOA - WHA 62.16 (ref 21).

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