Project Information Document/ Identification/Concept Stage (PID)

Concept Stage | Date Prepared/Updated: 25-Feb-2019 | Report No: PIDC127849

BASIC INFORMATION

A. Basic Project Data

Project ID	Parent Project ID (if any)	Environmental Assessment Category	Project Name
P165052		B - Partial Assessment (B)	Support to DRC human African trypanosomiasis control program
Region	**Country**	**Date PID Prepared**	**Estimated Date of Approval**
AFRICA	Congo, Democratic Republic of	25-Feb-2019	
Financing Instrument	**Borrower(s)**	**Implementing Agency**	**Initiation Note Review Decision**
Investment Project Financing	Drugs for Neglected Diseases Initiative (DNDi)	Drugs for Neglected Diseases Initiative - DRC	The review did authorize the preparation to continue

PROJECT FINANCING DATA (US$, Millions)

SUMMARY

Total Project Cost	0.00
Total Financing	0.00
Financing Gap	0.00

DETAILS

Non-World Bank Group Financing

Trust Funds	2.75
Japan Social Development Fund	2.75

B. Introduction and Context

Country Context

The Democratic Republic of the Congo (DRC), the largest country in Francophone Africa, has vast natural resources and spans a surface area of 2.3 million square kilometers. DRC's large (78.7 million) and young population (46.3% of the population is under 15) (2016), its vast natural resources, and large agricultural potential position it well for continued growth. However, political instability and weak state institutions have

severely limited the ability of successive governments to maintain and improve the living standard of the population in a post-conflict and fragile country with high demographic growth.

The country has gone through a period of significant growth with modest progress in poverty reduction, but recently the trend has slowed down. With an average economic growth of 7.5% over 2010-2015, DRC was one of the fastest growing economies in Africa. The poverty headcount rate decreased from 69.3% in 2005 to 64% in 2012, but with population growth, the number of poor increased by 7 million. It is estimated that the slowdown in economic growth in 2016 led to a decrease in real per capita GDP, with negative consequences for poverty reduction. Growth is projected to pick up again but at a lower rate than previously. The country is richly endowed with natural resources and extractive industries are one of the main sources of economic growth, representing around 24% of GDP. The agriculture sector remains the largest sector for employment, accounting for almost three-quarters of the total labor force. The tertiary and manufacturing sectors have both increased by over 4% since 2010. Population growth, insufficient macroeconomic growth, and unbalanced sectorial growth have combined to push a great many working-aged people into the informal sector, which accounted for 81.5% of employment in 2015.

The poor state of infrastructure remains a major constraint on sustainable, inclusive growth in the country.[1] Even by the standards of SSA, the country is at the bottom in almost all measures of infrastructure coverage.[2] Gaps are particularly large in road transport, electricity supply, and access to improved water sources.[3] The country is almost entirely landlocked, and the bad conditions of transportation infrastructures aggravate geographical isolation and the social and economic inequalities across provinces and between urban and rural areas.

Despite recent economic growth, institutions have been unable to deliver the policies to build the foundations of a strong, diversified, and resilient economy. Thus, the country's heavy dependence on natural resources makes it highly vulnerable to external shocks. DRC is experiencing significant fiscal stress due to the global economic slowdown and domestic political uncertainty with presidential elections having been postponed until December 2018. The production of oil and mining products during the first half of 2016 declined by 8.6% compared to 2015 and port activity declined by 17.6%. The drop in the global demand for raw materials resulted in decreased commodity prices and lower levels of economic activities, and greater risk of increased fiscal deficits. The decline in 2015 revenues led the government to cut the 2016 budget by 22% to keep spending under control. Despite these fiscally conservative measures, the budget balance turned to a negative US$260 million as of July 2016, from a surplus of US$90 million in July 2015. The overall economy has also been impacted: GDP growth declined from 9.5% in 2014 to 6.9% in 2015 and 2.2% in 2016.

Recent growth has not translated into improved human development outcomes for the Congolese population. Successive governments failed to make the needed investments to share the fruit of the recent growth with the poor Congolese people. The country remains among the poorest in the world with weak human development outcomes. It was ranked 176 out of 187 countries on the United Nations Human Development Index 2015 and DRC did not achieve any of its Millennium Development Goals by the end of 2015. 63% of the population is estimated to be poor, living on less than $1.25 per day. The country poverty is more than monetary: it includes a sense of exclusion, economic instability, and the inability to cope with uncertainties and plan for the future. Poverty is also experienced as the lack of economic opportunities and physical and psychological insecurity (World Bank Country Assistance Strategy, 2012).

Human development is a priority for the current government and some recent progress has been noted in selected health and education indicators, but considerable challenges remain. Investment in the provision of good quality social services (health, education) remains abysmally low. Public spending on health in DRC is low in absolute terms and by international standards (for example, DRC has 1/10th the total health expenditure of the SSA average) and the recent decline in domestic revenues has further worsened the priority given to the sector. The Ministry of Health budget dropped from 6.9% of the overall budget in 2014 to 4% in 2015 and 2016; the Government had to delay or only partially fulfill health sector expenditure commitments which jeopardizes the fragile gains in health outcomes in recent years. While public spending on health decreases, the share of the wage bill in total spending on health increased rapidly and reached 78% of total health budget in 2015, leaving only little resources to pay for other critical inputs.

[1] Country Economic Memorandum, vol. 3, 2012.

[2] WDI (World Development Indicators) (database), World Bank, Washington, DC, http://data.worldbank.org/data-catalog/world-development-indicators.

[3] See Foster and Benitez (2010).

Sectoral and Institutional Context

Donor	Status	Grant Amount (USD)	Activities Supported	Grant Period
BMGF	Committed	10,312,057	General grant: • Support completion of clinical development, nonclinical studies, and chemistry manufacturing controls	2015-2019

			(CMC) leading to the registration of fexinidazole • Support completion of clinical development, nonclinical studies, and CMC of acoziborole leading to registration <u>Supplemental grant:</u> • Provide vehicles and boats for 10 mobile teams to strengthen active HAT case detection across 14 health zones • Enhance the ability of 41 health facilities to detect and treat HAT in 15 health zones in the provinces of Kasai, Lomami and Tshopo • Contribute to the collection of epidemiological data in a centralized database maintained by PNLTHA • Expand clinical trial sites (FEX009 and OXA002) in DRC and Guinea	
DGIS-The Netherlands	Committed	1,750,000	• Support clinical trials for fexinidazole and acoziborole • Support registration of fexinidazole • Support HAT platform activities: annual meeting (partial)	2015-2020
BMBF/KFW-Germany	Committed	1,133,523	• Support clinical trials for fexinidazole and acoziborole • Support registration of fexinidazole • Support HAT platform activities: annual meeting (partial)	2016-2020
DFID- UK	Committed	2,272,727	• Support clinical trials for fexinidazole and acoziborole • Support registration of fexinidazole	2017-2020

			• Support HAT platform activities: annual meeting (partial)	
AFD-France	*Proposal*	*5,681,818*	*Implementation of fexinidazole and pharmaco-vigilance activities*	*2018-2020*

Human African trypanosomiasis (HAT), commonly known as sleeping sickness, is a public health problem in DRC. Twenty of the country's 26 provinces are endemic. Spread by the tsetse fly, HAT is a disease of the poorest of the poor in sub-Saharan Africa and primarily occurs in rural areas, where difficulty of diagnosis, political instability, and lack of access to health care, as well as weak health systems and disease surveillance capacity make estimates of disease prevalence difficult to ascertain. However, 19 countries have reported cases of HAT over the past decade. Patients with HAT and their families are often stigmatized, debilitated, and unable to work, pulling them further into poverty. Without treatment, HAT is almost systematically fatal. However, the JSDF funds will not be used for treatment.

HAT has been targeted for elimination as a public health problem by the World Health Organization (WHO) by 2020. Strengthened control and surveillance over the past 15 years have progressively reduced transmission of the disease – from approximately 10,000 cases identified in 2009 to a historic low of 2,184 cases in 2016. However, in the last ten years, over 75% of reported cases occurred in the DRC, making it the most affected country in the world. It is the only country that still reported more than 1,000 new cases annually in 2016.[1] Tackling HAT in DRC is therefore not only critical to the elimination of the disease but also for the development of rural areas where the disease is endemic.

[1] http://www.who.int/trypanosomiasis_african/news/HAT_elimination_on_track/en/

The population at risk of contracting sleeping sickness has been calculated for two five-year periods (2003–2007 and 2008–2012), resulting in estimates of 33 and 37 million people respectively. http://www.who.int/trypanosomiasis_african/resources/s12942-015-0013-9/en/

Box 1: HAT surveillance and control

Human African trypanosomiasis (HAT), also known as sleeping sickness, is a parasitic disease caused by protozoan parasites of the genus *Trypanosoma*. The disease is transmitted by tsetse flies, and is found in low-income, rural regions in sub-Saharan Africa.

It occurs in two stages: The early stage (stage 1) with non-specific symptoms, often un- or misdiagnosed and the late stage (stage 2) where the parasite crosses the blood-brain barrier, causing serious neurological disorders including sleep cycle disruptions, neurological manifestations, and progressive mental deterioration.

Without effective treatment, the disease is usually fatal. Early detection is critical: after the disease has advanced to the second stage, existing diagnostic and treatment procedures are painful, complicated, and/or risky.

Control and surveillance of the disease includes active and passive case finding, diagnosis, treatment, follow-up, vector control and control of the animal reservoir. These are performed at different levels and intensity, depending on the epidemiological situation, local and national capacity, and environment.

At present, **diagnosis of HAT** is done in fixed health units specifically trained and equipped (passive case detection) as well as by using mobile teams that travel to endemic areas and test community members (active case detection). There are several steps involved: 1) screening using serological tests and checking for clinical signs, especially swollen cervical lymph nodes to identify suspect cases. The tests used are the card agglutination test (CATT) or the recently introduced rapid diagnostic tests (RDT) for trypanosomiasis/*T.b. gambiense*. These tests are not specific enough for confirmation of infection, but they are helpful in identifying suspect cases that then are oriented towards 2) microscopy laboratory work to confirm presence of the disease. For parasitological confirmation, a cervical lymph node (if present) is punctured and the fluid examined; if absent or negative, then blood is drawn and examined using two concentration methods: Hematocrit Centrifugation Technique (HCT, or WOO test) and the mini Anion Exchange Centrifugation Technique (mAECT). Finally, 3) 'staging' with a lumbar puncture followed by microscopy assessment of parasites using the MSC (Modified Single Centrifugation) or WBC (White Blood Cell) count in cerebrospinal fluid is done to verify whether the disease has advanced to the central nervous system and what treatment is appropriate.

Treatment: The drugs used in the early stage (pentamidine or suramin) are safer or easier to administer than those for late stage but still require intramuscular injections and are ineffective for stage 2. The combination therapy nifurtimox-eflornithine (NECT), developed in 2009 by the Drugs for Neglected Diseases *initiative* (DND*i*) and partners, has replaced previous toxic treatments and is used to treat 100% of stage 2 HAT identified patients infected with *T.b. gambiense*, and has contributed to the fall in the case load. NECT is currently provided free of charge by WHO through the national health system, but treatment remains cumbersome, difficult to ship, store, and administer as it requires specialized hospital administration and trained staff (late stage patients need to be hospitalized for IV treatment). DND*i* is currently developing two new oral treatments for HAT, fexinidazole and acoziborole, which are both in advanced stages of development, and in combination with improved rapid diagnostic tests would shift the treatment paradigm. This change will be extremely helpful to reach WHO's elimination target and ensure its sustainability, particularly as HAT has a history of resurging after near elimination, which is what happened from 1960 to the end of the last century.

Significant progress has been made over the recent past: the number of HAT cases reported yearly from DRC decreased by 70 % from 2012 to 2016.[1] The National Sleeping Sickness Control Program (NSSCP or PNLTHA, the French acronym) manages the government's program to fight the disease. The NSSCP/PNLTHA

is geographically structured in 11 provincial coordination teams, each with one to seven mobile teams, based on HAT prevalence. Aside from active case finding, the mobile teams supervise fixed health structures, some of them specialized, other integrated in the general health system, performing diagnosis and treatment. [2] Coordinated efforts in data collection, reporting, management and mapping, supported by (WHO and culminating in the Atlas of HAT, have improved accuracy in estimates of HAT distribution and risk in DRC. A recent initiative, "TRYP ELIM," followed by its extension "TRYP-ELIM BANDUNDU" (Provinces of Kwilu, Mai-Ndombe, and Kwango), was developed with funding from the Bill & Melinda Gates Foundation (BMGF) and complemented in other provinces with the support of the Government of Belgium (totaling >75M USD). Implemented by the Institute of Tropical Medicine (Antwerp) and the DRC NSSCP/PNLTHA, it aims to catalyze and stabilize activities around HAT elimination in DRC, including digital data collection, quality system implementation, microplanning district by district using evidence to make decisions, and continuous improvement via internal and external review yearly. Finally, with the support of WHO (Equateur, Sud Ubangi, Nord Ubangui, Mongala and Sankuru) and FIND (Kongo Central), the NSSCP/PNLTHA engages in active and passive case detection as well as vector control in HAT endemic provinces (see Fig 1).

The HAT Platform -- an exchange network between research institutions, NGOs, product development partnership (PDPs), Ministry of Health officials, and WHO -- initiated DND*i* and the NSSCP/PNLTHA -- builds and strengthens capacity for diagnosis, treatment, and research in sleeping sickness-endemic countries. At present, DND*i* is collaborating with the NSSCP/PNLTHA to reinforce the technical and logistical capacities of 10 mobile teams in charge of active case finding and the technical capacities of fixed health structures in charge of passive case finding in areas where DND*i*'s clinical trials are implemented to ensure the best possible quantity and quality of case detection. The mobile teams functioning around DND*i*-supported clinical trial sites operate in Kwilu Province: Bandundu, Bagata, Masi-Manimba, Moyen Kwilu; Maï-Ndombe Province: Mushie, Kwamouth; East Kasai Province: Tshilenge, Cilomba; Lomami Province: N'Gandajika; and Tshopo Province: Isangi.

There is a careful division of the support given, discussed in coordination meetings chaired by the PNLTHA with the assistance of all above mentioned partners twice a year, to avoid duplications. Regular exchanges to coordinate among the various partners enable each partner to benefit from technical improvements and strategies and maximize impact.

[1] PNLTHA DRC Annual Report 2016

[2] Mobile teams have a target of 300 people screened per day with a monthly itinerancy of 20 days over 11 months (or 66000 people screened/year). Overall, the active case search examines above 2 million people per year. The teams are supposed to return every year to known endemic areas and to visit unexplored areas (of unknown endemicity) once every three years, so that coverage may be complete. A planning exercise to propose the areas (villages) to cover is conducted once a year.

Table 1: International partners in HAT-related activities in DRC

International PNLTHA Partner	Supported areas	Activities supported	Funding
WHO	Ubangi North, Ubangi South, Equateur; Mongala; Central Kasaï, Sankuru	Case detection; Treatment; Surveillance; Vector control	Sanofi; Bayer
PATH	Kwilu, Kwango, Maï-Ndombe	Management	BMGF
ITM	Kwilu, Kwango, Maï-Ndombe	Case Detection	BMGF
ITM	17 Remaining Endemic Provinces	Management; Case Detection	Belgian Govt (DGD)
FIND	Kongo Central (+ cross border with Congo and Angola)	Case detection	BMGF; DFID, KWF; SDC; Canton Gva
LSTM	Kwilu, (Maï-Ndombe planned)	Vector Control	BMGF
DND*i*	Kwilu, Maï-Ndombe, Tshopo, East Kasaï, Lomami	Case detection; Clinical trials	BMGF; DFID, KWF; DGIS; SDC; Canton Gva

Fig 1. New administrative chart showing the provinces proposed for intervention

Fig 2. Distribution of partner support to active and passive case finding in HAT endemic health zones in DRC

Ex-Bandundu province (52% of total cases reported during the period 2011-2015):

Health districts with DND*i* support for mobile teams and passive screening in study sites only. ITM-BMGF in charge of mini-mobile teams and reinforcement of passive screening in health system.

Health districts with ITM-BMGF support for mobile teams, mini-mobile teams, and reinforcement of passive screening in health system.

Kongo Central province (2% of total cases reported during the period 2011-2015):

Health districts with FIND support for the reinforcement of passive screening in health system and reactive active screening.

Ex-Equateur Nord province (3% of total cases reported during the period 2011-2015):

Health districts with WHO support for the reinforcement of passive screening in health system and ITM-DGD for active screening.

Rest of HAT endemic provinces (43% of total cases reported during the period 2011-2015):

Health districts with DND*i* support for mobile teams and the reinforcement of passive screening in health system.

Health districts with ITM-DGD support for mobile teams, mini-mobile teams, and the reinforcement of passive screening in health system.

Health districts with WHO support for mobile teams. ITM-DGD support for the reinforcement of passive screening in health system.

Health districts with no cases reported during the period 2000-2015.

However, more needs to be done to eliminate HAT in DRC. HAT remains entrenched in some provinces, most notably in Kwilu, Mai-Ndombe, and Kwango which constitute the historical Bandundu province (more than half of all new cases in DRC in 2016 and 2017).[1] Making further progress towards disease elimination requires effectively targeting populations at risk for diagnosis and treatment (JSDF funds will not finance activities leading to treatment of patients) and strengthened surveillance activities, especially in areas where the risk of infection remains high and where resurgence could occur. In addition to heightened surveillance, new drugs that simplify the current treatment regimen, as well as simple, rapid, and sensitive screening and diagnostic methods are needed to facilitate the integration of HAT control and elimination into the general health care system.

A new approach is needed to sustainably maintain case reduction until achieving disease elimination as targeted by WHO. At present, HAT is managed vertically in parallel to the general health system (the control program is based on widespread active case detection by 30 mobile teams as well as a network of specialized centers/referral hospitals for HAT diagnosis, treatment, and control, most of them based within districts). While the system has been highly effective, contributing to the significant reduction in number of cases detected, it is reaching its limits. First, as cases have dropped, existing active case detection activities have become less efficient, highlighting the need for a more effective approach to reach the less accessible endemic populations and detect cases in remote communities. Second, the verticality of the control program as well as the complexity of the existing diagnosis and treatment tools have prevented an appropriation by the health system of HAT case detection and patient care as general health system personnel avoid dealing with HAT and suspected cases are directly forwarded to the specialized teams, thus maintaining HAT as a special disease, to be treated outside mainstream health care structures. Integration of simple diagnostic techniques and a safe, effective, and easy to administer oral treatment in the general health system in tandem with improving and simplifying the existing active case detection strategies are needed to clear the most difficult foci.

[1] PNLTHA DRC Annual Report 2016 and 2017

A national strategic plan to eliminate the disease by 2020 is in development, with support from a consortium of partners, including the Antwerp Institute of Tropical Medicine from Belgium, BMGF, DND*i*, the Foundation for Innovative New Diagnostics (FIND), PATH, and WHO. The plan relies on active case detection (an awareness-raising campaign, digital technologies to help find and confirm cases; a cadre of "mini-mobile teams" going door-to-door to identify and map cases via the use of rapid diagnostic testing), and treatment as well as vector control (tsetse fly traps and tiny targets).[1] Additionally, new and easier to administer oral treatments will contribute significantly to HAT elimination.

[1] https://blog.path.org/2017/04/waking-from-sleeping-sickness-in-the-drc/

DND*i* is currently developing the first two oral treatments for HAT. Fexinidazole is the most advanced, already having completed three Phase 3 clinical trials: a pivotal trial in adults with stage 2 disease compared with the existing standard (NECT) and two complementary cohorts including adults with stage 1 HAT and children from 6 years of age, regardless of disease stage. A pivotal trial with adults is ongoing with DND*i*'s second new treatment in development, acoziborole. Both drugs – if successful – will be game-changing, treating both stages of the disease and enabling community- and ultimately village/home-based treatment, which will eliminate the need for painful lumbar punctures to diagnose stage 2 HAT, reduce the need for hospitalization, decrease the disruption and economic burden to the lives of the patients and their families whilst at the same time freeing certain health staff for other medical needs – and ultimately, putting HAT on the road toward sustainable elimination. Fexinidazole has been recently submitted for regulatory approval to the European Medicines Agency (EMA) and if granted, by the end of 2018 a large-scale implementation plan needs to be developed at community level. The JSDF funds will not be used to undertake clinical trials or treatment of patients/ beneficiaries. Treatment-related activities will be funded from other sources.

Figure 3: New oral treatments - Attributes of fexinidazole and acoziborole (formerly SCYX-7158)

The proposed JSDF grant would support community-based activities that will reinforce health system capacity for active and passive case detection, diagnosis, at the community level and strengthen the community's engagement in HAT surveillance and control. It will take advantage of recent developments simplifying case detection (rapid screening tests) and (development of two oral drugs) to extend HAT care

capacity within the mainstream health system, but without undermining the existing active case detection capacity.

No funds from the JSDF grant would go toward the conduct of clinical trials or treatment, as these activities are covered by other donors, and the JSDF grant would not duplicate in any way existing support DND*i* receives from other donors of its HAT program.

Table 2 – Existing donor support for DND*i* HAT program in DRC

Donor	Status	Grant Amount (USD)	Activities Supported	Grant Period
BMGF	Committed	10,312,057	General grant: • Support completion of clinical development, nonclinical studies, and chemistry manufacturing controls (CMC) leading to the registration of fexinidazole • Support completion of clinical development, nonclinical studies, and CMC of acoziborole leading to registration Supplemental grant: • Provide vehicles and boats for 10 mobile teams to strengthen active HAT case detection across 14 health zones • Enhance the ability of 41 health facilities to detect and treat HAT in 15 health zones in the provinces of Kasai, Lomami and Tshopo • Contribute to the collection of epidemiological data in a centralized database maintained by PNLTHA	2015-2019

			• Expand clinical trial sites (FEX009 and OXA002) in DRC and Guinea	
DGIS-The Netherlands	Committed	1,750,000	• Support clinical trials for fexinidazole and acoziborole • Support registration of fexinidazole • Support HAT platform activities: annual meeting (partial)	2015-2020
BMBF/KFW-Germany	Committed	1,133,523	• Support clinical trials for fexinidazole and acoziborole • Support registration of fexinidazole • Support HAT platform activities: annual meeting (partial)	2016-2020
DFID- UK	Committed	2,272,727	• Support clinical trials for fexinidazole and acoziborole • Support registration of fexinidazole • Support HAT platform activities: annual meeting (partial)	2017-2020
AFD-France	*Proposal*	*5,681,818*	*Implementation of fexinidazole and pharmaco-vigilance activities*	*2018-2020*

[1] http://www.who.int/trypanosomiasis_african/news/HAT_elimination_on_track/en/

The population at risk of contracting sleeping sickness has been calculated for two five-year periods (2003–2007 and 2008–2012), resulting in estimates of 33 and 37 million people respectively. http://www.who.int/trypanosomiasis_african/resources/s12942-015-0013-9/en/

[2] PNLTHA DRC Annual Report 2016

[3]Mobile teams have a target of 300 people screened per day with a monthly itinerancy of 20 days over 11 months (or 66000 people screened/year). Overall, the active case search examines above 2 million people per year. The teams are supposed to return every year to known endemic areas and to visit unexplored areas (of unknown endemicity) once every three years, so that coverage may be complete. A planning exercise to propose the areas (villages) to cover is conducted once a year.

[4] PNLTHA DRC Annual Report 2016 and 2017

[5] https://blog.path.org/2017/04/waking-from-sleeping-sickness-in-the-drc/

Relationship to CPF

The proposed project is aligned with the FY13-16 Country Assistance Strategy for the DRC (CAS, Report No. 66158-ZR), which has been extended to the end of FY17 after the 2015 CAS Performance and Learning Review. The FY13-FY16 CAS identified improved access to health services in targeted areas as one of the targeted outcomes under the "increase access to social services and raise human development indicators" strategic objective. Bank involvement in the health sector uses a two-pronged approach: improving governance, management, and financing of the sector while continuing to provide support to the delivery of essential services to the population. The proposed project supports delivery of HAT services to the population, excluding treatment.

The proposed intervention is also aligned with the recommendations detailed in Chapter 9 of the Strategic Country Diagnostic (Report No. 112733-ZR), **regarding the need to raise access to good-quality health care services** among other priorities, priorities that will translate into the Country Partnership Framework for 2018-2021 under preparation. The proposed project will contribute to improving community awareness of, access to and quality of HAT-related health services for vulnerable populations in DRC and strengthen the health system for HAT detection and management.

C. Project Development Objective(s)

Proposed Development Objective(s)

The proposed project development objective (PDO) is to leverage recent developments in HAT treatment and other control tools to improve access to HAT health services for affected communities in ten health zones within five targeted provinces of the DRC. The five selected provinces are Kwilu (ex-Bandundu), Mai-Ndombe (ex-Bandundu), East Kasaï, Lomami, and Tshopo, and the ten health zones proposed are Kwamouth, Mushie, Bolobo (part), Bandundu, Bagata, Masi Manimba (1), Moyen Kwilu (Djuma), Tshilenge, Cilomba, Ngandajika, Isangi, Yakusu, Yabaondo, and Opala. The ten health zones in the five targeted provinces have a combined estimated population of 1 million people, comprised of approximately 1072 villages. The estimated total target beneficiaries from these health zones is drawn from about 700 endemic villages, with an estimated population of 675,000, representing almost 70% of the total population within the ten health zones. The project aims to provide access to screening to 95% of the target population (641,000 people), estimating that 50% of them are women.

The PDO will be achieved by strengthening capacity at the peripheral health services level to detect and treat HAT using rapid diagnostic tests and the current standard of care and support uptake of new treatments once available. It will also strengthen community engagement in HAT detection and management so that affected communities understand the risk of HAT, participate in case detection activities, and facilitate implementation of new treatments.

Key Results

The Project will respond directly to the development needs of some of the most vulnerable rural communities in DRC by improving access to health services for HAT in targeted communities and improving Community Level Management of HAT.

As a results of the proposed interventions,

1. **At least 600 communities where HAT is endemic** will be more effectively reached with screening and diagnosis and will be active participants in HAT surveillance and control activities.
2. **At least 400 new health personnel of the HAT endemic areas** will be trained in disease detection and treatment mechanisms but not actual treatment of patient as well as understand the needs and expectations of the communities (bidirectional awareness raising).
3. **At least 400 local authorities (including health) at the provincial, district, and village level** will understand the appropriate steps needed for disease elimination as well as the tools that can be used to achieve it. They will catalyze community participation to HAT management.
4. Building on the existing reporting system, adding **local information on qualitative aspects, the project team and the health personnel** of the selected high endemicity areas will understand the local epidemiological risks and their evolution, including specific risks for men, women and children, related with their distribution of activities and interfaces between them and the tsetse flies. For example, women tend to work in agriculture, and their children are at risk of being bitten by the flies living at the edge of the riverine forest and fields.
5. As a spillover effect, technical and organizational improvement of HAT-related activities will contribute towards overall peripheral **health system strengthening** through increased linkages between health facilities and the communities they serve.

The PDO level indicators will be: (1) the percentage of the target population in the 10 health zones with access to HAT diagnosis at < 5km or < one-hour walk from a health facility; (2) the number of health services staff trained in case detection and case management, (3) increase in self-referred patients to the health structures (passive case search) as a percent of total people examined within the 10 selected health zones in 5 targeted provinces (*see* **Annex: Results Framework**).

The full Results Framework including M&E Methodology and data collection frequency will be provided during Appraisal**.**

D. Preliminary Description

Activities/Components

The project is designed to overcome key capacity gaps for HAT case detection and case management, in 10 health zones from Kwilu (ex-Bandundu), Mai-Ndombe (ex-Bandundu), East Kasaï, Lomami, and Tshopo provinces of DRC where HAT is endemic and DND*i* is the main partner of the national control program for control and surveillance of HAT, so as to improve targeted communities access to those services. These

efforts should **contribute to disease diagnosis and elimination, but treatment will be funded from other funding sources.**

Through Component 1, the project will strengthen capacity of the peripheral health system to deliver HAT services at the community level. It will reach remote communities that have not, to date, been effectively targeted to provide diagnosis as close as possible to where patients live, thereby contributing to reduce disease prevalence. Through Component 2, the project will strengthen community engagement in HAT surveillance and control, by using interventions such as information, education, and communication techniques.

The project is innovative as it will contribute to:

- Building new capacities among public services at the health zone level and reaching new beneficiaries who were not covered by existing programs and by building capacity for HAT services delivery into the mainstream health system at the peripheral level.
- Building new capacities among beneficiary groups by building knowledge around HAT and fostering demand generation for HAT-related services
- Bringing alternative ways of delivering services, more effectively and/or efficiently, to beneficiary populations, including fostering awareness of and extensive access to new oral treatments once approved but treatment will not be funded from the JSDF Project.

The project will also document experiences and results to inform future community-level interventions.

The proposed Project will finance the following three components:

Component 1: Strengthen capacity of the health system to deliver HAT services at the community level (USD 1.562 M) through screening and diagnosis but not treatment.

Subcomponent 1.1: Scale up capacity for active and passive case detection at the community level (USD 1.398 M)

Active screening: The project will support implementation of the Card Agglutination Test for Trypanosomiasis (CATT), or RDTs (Rapid Diagnostic Tests) both serological screening tests that allow for mass screening at the community level. Mobile teams are composed of community health workers (seven to nine people) for CATT complemented with mini-mobile teams (two technicians going door-to-door and screening people) for RDTs and both detect seropositive suspects that are later tested with a confirmatory parasitological test. Both CATTs and RDTs have been tested and deployed successfully in DRC. CATT and RDTs increase the performance of the final parasitological diagnosis by targeting only seropositive individuals, thus reducing the total numbers to be examined by microscopy. DND*i* currently supports 10 mobile teams who perform active case detection.

The project will supply these teams with 200,000 CATT tests per year for screening (about one third of total need). This grant will also support the purchase of 10 motorbikes to facilitate transportation to remote areas

for members of the mobile teams performing screening activities with RDTs in difficult to access areas and in non-permanent settlements in endemic areas that cannot be reached by car. At present, teams can go to villages but cannot access hard-to-reach 'encampments' where mini-mobile teams are needed due to high risk of transmission. This complements, but does not duplicate, existing support from the BMGF for cars and boats for the mobile teams.

There is also a need to strengthen passive case detection and diagnosis at the peripheral health facility level. In known areas of endemicity, the capacity of peripheral health centers should be strengthened/developed for local detection of cases. Even if in some cases these structures exist and are well-identified, they often lack the tools and trained staff to deliver on this objective. This capacity strengthening activity will focus on those identified community health centers and provide them with the tools and training to identify, among people self-presenting for health services, individuals with signs and symptoms suggestive of HAT, screen, and diagnose them and, if confirmed, recommend treatment with the most effective treatment available. However, treatment will not be funded from the JSDF grant resources. This will include upgrading of equipment and supplies (10 microscopes, other equipment as needed, 20,000 rapid screening tests per year, and additional lab consumables packages (e.g. disposable gloves, syringes, etc.) for 20 health centers for screening and diagnosis), training of health care personnel at the community level to use diagnostic tools , installing solar energy systems in 10 facilities given limited access to electricity in those areas, as well as additional rehabilitation and maintenance of selected community health centers and posts (5 health centers and 5 health posts per year over three years). It will ensure that the selected health facilities can provide adequate care [but treatment would not be funded from the JSDF Project] to all identified HAT patients in their community. Care will be taken in the selection of facilities to be supported through this grant to avoid any overlap with support from other donors also contributing to these activities. Selection will be finalized by appraisal.

Subcomponent 1.2.: Build capacity of the health system for the introduction of new treatments at the community level (USD 0.164 M)

While the JSDF will not finance activities related to treatment, it is worth mentioning that the first oral treatment for HAT (fexinidazole), developed by DND*i* and partners are specifically designed to be adapted for use in the remote settings in which HAT is found in DRC, is anticipated to be approved and introduced into the DRC health system by the end of 2018 or the beginning of 2019. This will create a paradigm change in how HAT is treated as this is the first time that patients can be directly involved in HAT treatment in contrast to the past where the treatment could never be self-administered. It will require a parallel update in guidelines for patient care and treatment at the national level. While JSDF funds will not be used to implement the introduction of new oral treatment, that needs to be supported by other donors rather than via the JSDF which cannot finance treatment. This activity will support the development and introduction of new treatment guidelines via district health teams, development of training materials and training of health zone authorities and staff on new treatment protocols (one training organized per year in each province up to a total of 15 sessions) to ensure that once new treatments are made available through the health system, they are also used appropriately. This is a fully new activity unsupported by any existing donor.

Component 2: Strengthen community engagement in HAT surveillance and control towards elimination. (USD 0.910 M)

The mobile teams are the cornerstone of the active case detection strategy in DRC. However, some individuals screened by the mobile teams may not be detected at the time of the screening for any number of reasons. Therefore, educating targeted communities and engaging them as active participants to identify signs and symptoms of HAT and refer the suspected persons for HAT case detection and case management, are critical to ensure progress. Through this component, an effective approach will be devised to engage the community in surveillance and control activities on an ongoing basis and make them part of the continuum of the HAT control system.

Subcomponent 2.1: Assessment of Community Knowledge and Behavior related to HAT Prevention, Diagnosis and Treatment (USD 0.222 M)

Community assessment has not been done systematically in DRC, although several studies have reported on the main beliefs and community reactions to previous treatments, mainly on the barriers to acceptance of participation in mobile activities when melarsoprol was the main (and very toxic) treatment for the second stage of the disease. Past studies, in that context, have found that sociocultural factors can be important barriers to screening and treatment seeking behavior.[1]

This sub-component will provide support for a baseline social behavioral assessment to be conducted in the five targeted regions to better understand the current sociocultural barriers to health seeking behavior (including gender-specific behavior), knowledge of HAT infection and treatment options, and determine appropriate interventions, to be funded from other sources, that are also gender-informed to address them. This baseline assessment expects to use key informant interviews and focus group discussions rather than a survey methodology, not only to ensure timely availability of the results and information to guide future activities but also to ensure active participation of the targeted beneficiary communities/groups. The baseline assessment will be conducted by a consultant(s) with experience in the health sector and expertise in community engagement and behavior change communication, supported by local health care workers to maintain the link for future health care services, and will ensure that representatives of different community groups are met separately, as necessary, to ensure transparency, comfort, and ownership by the community.

The choice of communities to assess will be based on existing information, available at the PNLTHA, from the past mobile teams' activities, including participation data in each target area, as well as the detected prevalence (number of cases in the selected villages in the three previous years). This quantitative information will be complemented with the qualitative analysis about the perception of the disease and the present understanding of the available treatment solutions, but actual treatment will be funded from other sources. It will examine specific vulnerable groups, including women and children. Detailed baseline and endline studies are under the M&E Section.

[1] *Should I Get Screened for Sleeping Sickness? A Qualitative Study in Kasai Province, Democratic Republic of Congo*, Alain Mpanya, David Hendrickx et al., Jan. 2012 available at http://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0001467

Baseline and Endline Studies:

The baseline assessment will inform the design of specific interventions that might include activities at the community level such as: workshops and demonstration events related to information and education campaigns (IEC); community activities targeting beliefs and harmful social norms that contribute towards greater HAT exposure or delay treatment thus increasing the risk of transmission and delaying disease elimination; psychosocial support for affected patients, etc. The baseline assessment will also inform what type of accompanying behavioral interventions or messaging would best support the introduction of the new HAT treatments to be funded from other sources.

At the end of the grant period, a post-intervention social behavioral assessment will be performed in the targeted endemic communities, again considering specific feedback from different vulnerable groups to evaluate changes in perception and behavior. Success shall be positive changes in behavior and perception about HAT prevention, diagnosis and treatment and utilization of local health services which would contribute to a steep reduction or even absence of new cases in the targeted communities. A specific assessment tool will be designed to measure this impact.

The sub-component will provide support for a consultant(s) with the appropriate qualifications (monitoring and evaluation, social science, community engagement and behavior change communication) and with experience in conducting similar assessments in the health sector. The detailed request for proposals will outline the minimum specifications of coverage for focus groups and interviews within the provinces to ensure that there are sufficient inputs from the intended beneficiaries.

The baseline and post-intervention assessment results will be shared with the PNLTHA and partners involved in DRC HAT control activities and integrated into the training provided under sub-component 2.2 as outlined below.

Subcomponent 2.2: Support community participation in HAT case detection, monitoring and surveillance (USD 0.688 M)

As part of building the local capacity, the project will support interventions to encourage greater community participation to identify and self-refer suspect cases to community health centers in between visits from the mobile teams, hence fostering community-level case detection, monitoring and surveillance so that affected patients can be detected early and cared for effectively. These interventions will be targeted towards increasing community use of local health services by improving knowledge and reducing practices and harmful behaviors at the community level that limit health seeking behavior and result in increased HAT vulnerability.

The interventions will be designed based on results of the social behavioral assessment in sub-component 2.1, taking into consideration all the inputs from the communities as well as local health personnel engaged in the process, and then implemented with the support of the NSSCP/PNLTHA, provincial, district, and local health authorities as well as community key opinion leaders (KOLs), such as chiefs, traditional healers, village elders, or women at the community level. IEC campaigns and messaging would be appropriately targeted at the local and health facility level, through community radio stations or similar locally accessible means**.**

A training cascade approach will be used to train provincial and district staff as trainers of trainers (TOT), which will then train the health zone personnel. Trained local health officers would then engage with and train community KOLs, who would then be equipped to provide guidance to their specific community groups. In addition, the mobile teams will also play an important role of engaging community KOLs, including special outreach activities to traditional healers. Traditional healers play a very important role in these communities as most patients first go to traditional healers, which can delay diagnosis and access to treatment, so close coordination and collaboration with this dimension will be critical.

The KOLs will act in conjunction with local health officers to provide communities with correct health information regarding HAT, the most up to date treatment and training on the clinical symptoms of HAT, thereby contributing to improving case detection and reducing the stigma associated with the disease. As necessary, particularly at the local/community level, the TOT training may necessitate some gender disaggregated training to allow appropriate cultural and social norms to be followed to improve the acceptability of the training and messaging. The sub-component will also provide support for materials required for the IEC campaign and tools and documents needed for trainings.

The sub-component will provide support for the two community-based learning specialists who will conduct one national level training of trainers (TOT) session with the support of the baseline assessment consultant(s) for provincial level health personnel. Then the trained provincial TOTs would conduct two training sessions with their relevant district and local health personnel. District- and local-level health personnel would then train KOLs in their health zones so that the KOLs are able to also share that information accurately within their communities. KOLs trained in these sessions would be expected to disseminate the information shared within their communities through their own community activities. It is expected that there would be at least three KOL training sessions in each of the targeted provinces and then the KOLs would subsequently be involved in multiple activities/events to disseminate the information to their communities and ensure greater distribution of the information. Combined, there should be one national TOT session, two sessions in each province (total 10), and 30 sequences at the health zone or KOL level after the end of the assessment.

Training of trainers (TOT)

- Place: Kinshasa
- Trainers: Project Coordinator; baseline assessment consultants (two); two Community-based Learning Specialists

- Trainees: Four (4) Provincial HAT Coordinators and four (4) Supervisors (East Kasaï and Lomami are covered by one coordinator); Five (5) Persons from Provincial Direction of Health in charge of community-based activities (Provincial supervisor); 10 district supervisors from involved health zones
- Duration: Three (3) days

Training health staff (facilitators)

- Place: Each provincial capital except Lomami, as they will join at Mbuji Mayi
- Trainers: One National baseline consultant; one Community-Based Learning Specialists; one Provincial HAT Supervisor; one Provincial Supervisor; one District Supervisor per health zone
- Trainees: Up to 30 (including staff from the peripheral health structures and community mobilizers from the health teams) that will be identified during the assessment per province.
- Duration: Two (2) days

Training Key opinion leaders (KOLs) at health zone level

- Place: At each health zone headquarters
- Trainers: One community-based learning specialist; one district supervisor; one or two community mobilizer(s) from the directly involved mobile teams
- Trainees: Up to 30 KOLs from the villages of a given health zone
- Duration: Two days

Community-level interventions facilitated by the KOLs will be continuous starting the second year of the project. They will not be formally programmed as they would be “opportunistic” to take advantage of other community-based events, engagements and activities and the availability of mobile teams and health zone officials. These interventions incorporate the use of locally available media both for dissemination and information purposes. The specific examples of these interventions will be more clearly defined based on the baseline social behavioral assessment.

- Place: At each village center at least two activities per community per health zone. Overall, it is expected that there shall be over 600 community-level activities over the three years.
- Trainers: One community-based learning specialist and/or one district supervisor and/or one community mobilizer from the directly involved mobile teams if the team is in their scheduled route at the village or nearby. Ideally, there should be at least five KOL per event, one to two of them trained under the program.
- Trainees: All villagers that show up; water to be provided
- Duration: Two to three hours
- Content: Community meetings; theatre; sport events; side training during HAT active case search or other health system activities (vaccination campaigns…)

At the community level there will also be home based visits and case search, and specific support for patient referral to diagnostics and treatment centers.

Component 3: Project Management and Administration, Monitoring and Evaluation, and Knowledge Dissemination. (USD 0.277 M)

Subcomponent 3.1: Project Management and Administration (PMA) (USD 0.207 M)

This component will finance the provision of goods, consultant services, training, and operating costs to support project monitoring, evaluation, and management, with an aim to ensure efficient, effective, transparent, and accountable delivery of this project. The project implementation unit (PIU) will be the DND*i* office in Kinshasa and will be composed primarily of DND*i* staff, with capabilities added through hiring of consultants, as needed. The project will be overseen by an overall project coordinator (international DND*i* staff) together with the Kinshasa Head of Office (country-level coordination and supervision). The Grant financial management (FM) and procurement functions will be ensured respectively by DND*i*'s FM staff and Logistics Officer, which is responsible for procurement, and supported by a Procurement Specialist (to be added if necessary). Final project management arrangements, together with any additional fiduciary capacity needs, will be confirmed during Appraisal.

The project will also finance the mandatory external audits (for each of the four expected years of the project life cycle), Project Launch, Mid-Term Review and closing activities, and the Implementation Completion Report (ICR).

Subcomponent 3.2: Monitoring and Evaluation (USD 0.070 M)

The monitoring and evaluation of final outcomes and results under component 1 are embedded within the component activities, while the endline assessment as well health screening data will provide outcomes and results for component 2. These qualitative and quantitative outcomes together with the medical results achieved during implementation will be combined in the final report by the Implementing Agency to provide an overall picture of the impact of the project. Therefore, there will be no impact evaluation necessary to be conducted**.** M&E arrangements will include participatory monitoring of the activities by the beneficiaries through regular consultations on project implementation. Beneficiary inputs will be collected routinely through KOL interviews during field visits by the project trained personnel, to gain the views of intended beneficiaries regarding the impact of the project interventions.

DNDi has existing M&E staff for collecting and reviewing data related to the grant outcomes that have been the main focus of their current activities and can easily support the collection of necessary data for activities under Component 1. These staff will be supplemented by the recruitment of an additional M&E specialist, who would be responsible for coordinating component 2 activities, reviewing and enhancing the participatory monitoring data (design a beneficiary survey and work with mobile teams to administer it), and collecting and analyzing data for the overall project results framework.

Subcomponent 3.3: Knowledge Dissemination (USD 0.000 M - covered by existing DNDi budget)

The project will develop good practice notes on community engagement in disease surveillance and control (directly related to this project) and introduction of new treatment mechanisms at the community level and the associated risks with this introduction but not actual administration of the drugs which cannot be funded from the JSDF funds. These will inform policy discussion and scale up of interventions that effectively engage communities in low-resource settings through World Bank or other support. Results and experiences will be disseminated through the HAT Platform newsletters, scientific conferences, and publications in peer-reviewed journals. A specific mass media communication strategy (at national and international level) will also be developed, including visits to the field. Knowledge dissemination will be managed through the vehicle of the existing HAT platform (by its coordinator) and DND*i* staff. These costs will not be covered by the JSDF grant as they are part of ongoing DND*i* project activities and adequately supported at present. However, activities related to treatment would not be funded from the project activities.

The experience of community intervention to strengthen capacity for disease surveillance through screening and diagnoses of disease will be shared internally at DND*i* and adapted to other disease programs and contexts (Leishmaniasis, Chagas, Onchocerciasis, Mycetoma, Pediatric HIV, and Hepatitis C teams, working in other countries in Africa, Latin America, and Asia) within the regular R&D monthly meetings. Within the HAT team, a parallel intervention is being planned at the community level in Uganda and Malawi in the context of the extension of new treatments to the *T.b. rhodesiense* endemic areas.

One HAT Platform newsletter per year will include updated information about the project evolution and further presentations on specific information (baseline, project implementation evolution, challenges, and solutions found) will take place annually alternating scientific meetings as the HAT Platform-EANETT (East African Network for Tsetse and Trypanosomosis) and the ISCTRC (International Scientific Council for Trypanosomiasis Research and Control) conferences organized by the African Union in alternate years. HAT Platform-EANETT in 2018 and 2020 and ISCTRC in 2019. The Partners of the NSSCP/PNLTHA, including WHO, FIND, IRD and IMT, usually meet twice a year to share experiences and clarify the destination of their financial support within the programmed activities. They support different mobile case detection teams, but always keeping the same terms and conditions as established by the PNLTHA to avoid differences among staff in payments or equipment. These meetings will certainly be relevant to discuss content and adapt strategies regarding other partners' input and results.

The first component of this project will be implemented over 3 years, and the second component will start the first year with the assessment and the second year with training and implementation. End-line report will be prepared at the beginning of the fourth year. The full project through the Closing date will allow for 4 years to accommodate for feedback to the local authorities and communities, delays in implementation and possible lags in activities and avoid transaction costs to extend the closing deadline.

SAFEGUARDS

E. Safeguard Policies that Might Apply

Safeguard Policies Triggered by the Project	Yes	No	TBD
Environmental Assessment OP/BP 4.01	X		
Natural Habitats OP/BP 4.04		X	
Forests OP/BP 4.36		X	
Pest Management OP 4.09		X	
Physical Cultural Resources OP/BP 4.11		X	
Indigenous Peoples OP/BP 4.10		X	
Involuntary Resettlement OP/BP 4.12		X	
Safety of Dams OP/BP 4.37		X	
Projects on International Waterways OP/BP 7.50		X	
Projects in Disputed Areas OP/BP 7.60		X	

Summary of Screening of Environmental and Social Risks and Impacts

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